In The United States District Court

For the Eastern District of Michigan

ANNE MITCHELL,

(Relator) Plaintiff,

v.

Case No. 2: 11-cv-10090

Hon. Justice Victoria Roberts

UNITED MEDICAL SYSTEMS, INC., et al,

Defendants,

MOTION FOR REOPENING FILE (COMPLAINT), AND MOTION TO REQUEST COURT-APPOINTED COUNSEL

Anne Mitchell (RELATOR), *Plaintiff pro se*, respectfully requests that this court grant the above noted case file to be reopened. Having received wholly inadequate, incompetent, and improper legal representation by previous counsel, attorneys Monica P. Navarro, Louis Szura, and Suzanne Nolan and the law offices of Frank, Haron, Weiner, and Navarro PLC, the mess created by these attorneys in this complaint made a just result impossible to achieve. This mess created both by imprecise, incomplete construction and faulty execution of this complaint has disadvantaged any means for me to obtain any proper legal representation to support my claims or to prosecute these claims on my own, and I thereby respectfully request this court to grant court-appointed counsel for me to prosecute and pursue rightful claims in this complaint. In support of this motion *Plaintiff* states the following:

1. As the relator in this case, compelled by my conscience, it was an obvious presumption to me that the public interest overrode the selfish interests of the company and industry I served, and

that the act of "whistleblowing" would be my professional suicide but was the only means for achieving peace of mind following discovery of my own unwitting participation in deadly, horrific medical fraud purposely and painstakingly hidden from public view,

2. I discovered widely corrupt, highly contemptible, fraudulent, conspiratorial, masterfully concealed, illegal, distinctly harmful, and morally indefensible activity adversely affecting the medical care and endangering the lives of millions of U.S. citizens,

3. My complaint was meant entirely to inform and warn the government of a serious and significant safety issue, - costly, excessive, unnecessary, and intentional endangerment of people's lives - fully knowing that the government had no knowledge of the obfuscated extent of the harm, fraud, and the cover-up by the Defendants acting in concert. The "False Claims" in my complaint were made when urologists and their conspirators claimed and broadly misrepresented that UESWL is "safe," all the while ***knowing*** it is unsafe. They made these "False Claims," ***lying*** in calculated and strategic ways in order to gain extraordinary fraudulent profit from the government and taxpayers,

4. My attorneys did not clearly, openly, and honestly represent my claims in the complaint filed on my behalf, and did this by partially basing their faulty assessment/legal judgment to be lack of my "standing" to reveal reckless life-altering patient endangerment and serious safety problems,

5. When the U.S. Department of Justice determines whether to intervene based on a relator's information, if the relator's attorneys have improperly and incompetently misrepresented the relator's disclosures which were specifically critical to the singular cause at all for legal action both in the case filing and in critical communications to the DOJ, it becomes impossible for the DOJ to make an informed decision to intervene based on the facts of the case as rendered by the relator.

6. Following being *forced* to "voluntarily" request dismissal of the case by my attorneys whom expressed explicitly to me that I would never again be able to find another attorney to prosecute the complaint, I began an unending effort to find legal representation. In the meantime I have gone public as best I can with my very serious assertions concerning the serious nature of the harm, fraud, and frightening patient safety issues being concealed by the Defendants which had not been properly incorporated by my attorneys as I'd always intended and asserted within the original complaint,

7. Losing any belief in what I'd determined was a distinctly hopeless structural bias in our civil courts that disadvantages claimants such as me the common affordability of competent legal representation, I filed a complaint on my own with the U.S. Food and Drug Administration (Case # CDRH CPT 1300384) that is currently under serious open investigation beginning when I filed it in July 2013. Knowing this, several of the Defendants have tried feverishly to sell their off their major operations in the past year, and two of them have successfully sold themselves off to likely unsuspecting hedge fund managers who are indeed very strange bed-fellows for such enterprises,

8. My deeply held belief is that what I discovered in this case is not merely civil fraud based on highly unusual kickbacks paid to urologists for performing UESWL, but includes the distinctly criminal acts of widespread and intentional patient endangerment, intentional life-threatening/altering public deception, and masterful collusion and deception by urologists and others in the cover-up. Concealing deleterious medical fraud via organized, intentional, planned, strategic activity disguised as "financial innovation," in a painstaking, cunning, highly sophisticated, large-scale and outrageously contemptuous one-sided game played with reckless abandon, this organized "mob" gravely endangers the lives of their easy prey. They grant themselves improper broad discretion to mask, neglect, and ignore the known dangers. They

"sell" their patients on the UESWL procedure, on its "effectiveness,' on its "routine use," but purposely, masterfully cover their tracks about safe use to the best of their abilities in signed patient consent forms. The unsuspecting pawns (vulnerable patients) in their cold, calculated scheme year after year are plucked off *en masse* without transparent, ethical, honest risk disclosure. Medical research is entirely dishonest, deceptive, or simply not disclosed or attempted in order to protect exposure of the truth about known UESWL dangers or about the covert brokering of patients. Skillfully and swiftly each rook, knight, bishop, queen, and king are "checked," *paid off* that is, by means that thwart any reasonable authority from competently questioning their motives or recognizing the costly, life-altering dangers and highly uncommon and unnecessary risks being posed to human life by their actions,

9. I believe this complaint as written should not only have reflected my distinctly serious assertions of a widespread cover-up of patient endangerment and distinctly unsafe medical care, but should have been competently filed by my attorneys under ***Racketeer-Influenced Corrupt Organization (RICO)*** status as well to have accurately represented my claims,

10. Without government acknowledgement of this highly deceptive and comprehensively organized charade concealing highly corrupted medical judgment, and without critical intervention by authorities, these extensive, overpowering, and malicious acts continue to inflict both fraud and unnecessary harm at outrageous cost beyond measure on innocent and vulnerable people every day,

11. Falsely claiming "safety" when the all the clinical evidence seriously contradicts it, by causing improper use and misinformed labelling of the devices, crafting highly deceptive and fraudulent medical research, and intentionally neglecting to honestly disclose and properly represent clearly known critical facts about patient safety and dangerous life-altering risks either by responsibly engaging the FDA or by obtaining properly informed patient consent, have caused *False Claims*

to be filed not only against government healthcare programs but against millions of taxpayers who fund the government.

12. Money gained by the conspirators in this scheme is used to purchase and protect legislation and policies, such as the *"Fair Market Value" Safe Harbor* exception for "non-provider-physician-owners" within the *Anti-Kickback Law*, serving the distinct and intentional purpose for concealing corrupt, dangerous, and outlandishly broad and harmful clinical discretion. This financial "battle cry" they have established in effort to assert entitlement to participate in the "business" of medicine as middlemen of sorts is used outwardly to subvert the medical truths, to "protect the (medical) evidence" of UESWL. It is a diversionary tactic that steers an otherwise distinctly medical conversation abruptly instead to focus on rights for physicians to financial gains through "structured arrangements" beyond their professional fees for patient referrals. By miring those others who are medically ill-equipped to interpret the clinical facts of this UESWL procedure in a controversy about asserting financial rights of urologists, they are cleverly able to corrupt and sideline the most relevant, pertinent, and serious conversation about their participation in deceptive, costly, and dangerously corrupted patient care now for the past thirty years. It is the perfect boondoggle, an elite swindle, and these highly intelligent bullies take great pride in it. This "Safe-Harbor" carve-out provision has been masterfully construed to protect wide-spread medical fraud and deception concerning the unsafe UESWL procedure and to support this pervasive *Racket's* ability with *carte blanche* to continue concealing deeply troubling medical facts which ***unnecessarily*** endanger patients' lives at great cost without their properly informed consent: for the money.

Separate "Brief" material shall be provided in support of these requests.

WHEREFORE, Plaintiff Anne Mitchell, pro se, in the cause of justice respectfully requests that this Court enter Orders granting (1) Reinstatement of this case by reopening this file, and (2) Assignment of competent Court-Appointed Plaintiff Counsel.

Respectfully submitted,

Anne Mitchell, Plaintiff

Anne Mitchell
PO Box 3249
Oak Park, IL 60303
(708) 763-0501 Phone
ae_mitchell@comcast.net

August 1, 2014

In The United States District Court

For the Eastern District of Michigan

ANNE MITCHELL,

(Relator) Plaintiff,

v.

Case No. 2: 11-cv-10090

Hon. Justice Victoria Roberts

UNITED MEDICAL SYSTEMS, INC., et al,

Defendants,

EXPLANATION AND SUPPORTING DOCUMENTATION (BRIEF)

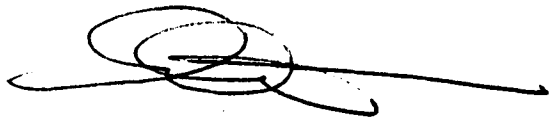
This submission of supporting documentation, pages 01-0287, accompanying the Motion for Reopening the File (Complaint) includes communications, publications, and records which demonstrate facts and rationale for reopening the complaint.

Merely arguing successfully that a business "arrangement" is "properly structured" does not address the seriousness of allegations of widespread intentional, negligent, unnecessary patient endangerment as a means to gaining highly unusual business success. The financial operation *is* both the means and the purpose for the deception, the disguise, and the costly endangerment. The highly organized, industry-wide financial operations are the purpose for keeping the operation impenetrable and the deadly secret, well, secret. A kickback is a kickback because it is as a duck. If it walks like a duck and quacks like a duck it is a duck.

Incompetent representation by counsel, neglecting or failing to recognize and to disclose the most material and substantive nature of the complaint, and/or not being adequately prepared to address the

complex nature of the complaint resulted in my representative counsel not acting in my best interest nor in the best interest of the public, therefore causing a massive scope of undue harm.

Respectfully submitted,



Anne Mitchell, Plaintiff

Anne Mitchell

PO Box 3249

Oak Park, IL 60303

(708) 763-0501 Phone

[illegible]

August 1, 2014

STATE OF MICHIGAN

ATTORNEY GRIEVANCE COMMISSION

BUHL BUILDING
535 GRISWOLD, SUITE 1700
DETROIT, MICHIGAN 48226
TELEPHONE (313) 961-6585
WWW.AGCMI.COM

June 11, 2014

PERSONAL AND CONFIDENTIAL
Ms. Anne E. Mitchell
P.O. Box 3249
Oak Park, IL 60303

RE: Anne E. Mitchell as to Monica P. Navarro
AGC File No. 1039-14

Dear Ms. Mitchell:

This office received your Request for Investigation, however, the allegations in your complaint are insufficient to warrant review by the Commission. Accordingly, after careful review by the staff, this matter is being closed under the authority of the Grievance Administrator pursuant to Michigan Court Rule 9.112 (C)(1) (a).

The Attorney Grievance Commission is not authorized to perform what is essentially a judicial function. We have evaluated each of your allegations and have determined that they do not involve a violation of the court rules enforced by this office. If you believe that your attorney engaged in legal malpractice, or gave you poor advice, you have the opportunity to bring the matter to the attention of the court. However, failure to achieve a result which you would term successful is not, by itself, evidence of misconduct. The disciplinary system is not designed to act as a substitute for your judicial or appellate remedies.

Ms. Navarro has been provided with a copy of your Request for Investigation. If my staff or I can be of service to you in the future, please do not hesitate to contact us again.

Very truly yours,

Ruthann Stevens
Senior Associate Counsel

RS/de
cc: Monica P. Navarro
Enclosure

11-CV-10090

HON VICTORIA ROBERTS

000001

{Reject-R4RI.doc}

~~000002~~

Anne Mitchell
PO Box 3249
Oak Park, IL 60303
April 7, 2014

Michigan Attorney Grievance Commission
Attn: Ms. Ruthann Stevens, esq.
Complaint Intake
243 West Congress, Suite 256
Detroit, MI 48226-3259

RE: Request for Investigation of Attorney **Monica P. Navarro** in: *United States of America, The States of Illinois, Indiana, Michigan, ex rel Anne Mitchell v. United Medical Systems (DE), et al. In the United States District Court for the Eastern District of Michigan Case No. 11-10090 (formerly Case No. 10C-6793 in N.D. Illinois)*

Dear Ms. Stevens and AGCMI:

To better formulate my *Request for Investigation* according to your process as you described in your letters to me of March 25, 2014 and April 1, 2014, I hereby submit the following to you.

You are aware that I have a substantial amount of documentation concerning my assertions about my complaint, since I had originally submitted this in my first attempt at filing my request with your office. At this time I shall not overwhelm you with these, but know that they are available to you as you see fit.

In 2010, I contracted with the offices of Frank, Haron, Weiner, and Navarro, 5435 Corporate Drive, Suite 225, Troy, MI 48098-2624 to represent me in the complaint mentioned above. A team from within their law practice comprised as I am aware of Susan D. Nolan, Louis C. Szura, and Monica P. Navarro worked together on my complaint, and at times I communicated directly with each of them individually and together.

I want to be clear that I liked these attorneys very much – all of them. But I do not believe that in the end they represented me and my complaint as I had clearly asserted or as I had clearly intended. I firmly believe they misinformed me concerning my legal standing in the complaint, and the resulting injury to me and to all those I had intended to inform by my actions as an informant/whistleblower is grave and substantial. I believe by my attorneys mishandling my complaint it in this manner or in manners not known to me, my *qui tam* complaint was forced to dismissal. It is also possible that something sinister may have happened when Thomas E. Zeno, the thirty-year veteran and Head of the Healthcare Fraud division of the US DOJ left to work for Defendants under employ by the firm *Squires Sanders* while my case was being investigated in his Washington, DC office. It is for this reason I am requesting action by your Commission. *Something* went terribly wrong.

Mr. Szura was my principal point of contact during and throughout the process from development of the case to his final demand that I "voluntarily" dismiss the case. **It was my belief that Ms. Navarro oversaw activities, provided guidance, and interjected her knowledge and opinions about my case as the senior partner in the firm.** It is my belief that Ms. Nolan acted as a subject matter expert, researched my complaint, and worked tirelessly drafting my complaint for submission. I do not know who of the three was responsible for decisions concerning my complaint. I don't know who of them decided I did not have "legal standing" to disclose the serious cover-up scheme of the dangerous patient safety issues related to *Urinary Extracorporeal Shockwave Lithotripsy (UESWL)* within my qui tam complaint.

Ms. Navarro was recommended to me by Mr. Patrick Burns from the organization *Taxpayer's Against Fraud* in Washington, DC, first when I was seeking a specialized *qui tam* attorney. He had also given me the names of two other attorneys, but I contacted **Ms. Navarro** first, spoke with her at length first on the phone before she invited me to the office of Frank, Haron, Weiner, and Navarro to meet with her, Mr. Szura, and Ms. Nolan. Though I did speak with the other *TAF* recommended attorneys prior to contracting with Ms. Navarro's firm, I believed that Ms. Navarro had a far better handle on understanding my complaint than the others. After I'd met with them at their Troy, Michigan office, I do not know with any certainty what role **Ms. Navarro** played or continued to play in my case other than as a senior advisor or firm partner. I chose their firm because of her and the initial communications I had with her specifically believing that they were best suited and knowledgeable to prosecute my case. During the time following their remission of my complaint to the court, the firm first called "*Frank, Haron, Weiner, and Navarro*" became "*Frank, Haron, Weiner*" without the "*Navarro*." I don't know why this happened, but it was my distinct understanding that **Ms. Navarro** remained "*of counsel*" for the firm and did remain an active participant in my *qui tam* complaint until I was forced to "voluntarily" dismiss the case.

It is my understanding from phone conversations with both Mr. Szura and Ms. Navarro that Susan Nolan worked very hard on researching and drafting the complaint itself, and that is the extent of my knowledge of Ms. Nolan's participation. However, I am unaware precisely of how it was decided and who decided to develop, draft, and execute my complaint in the manner in which it was done. I do not know how each of the members of this team participated behind the scenes in the decisions that had to have been made to execute my complaint in the manner in which they decided it was to be drafted and executed.

I stood forward by seeking legal counsel's protection from the law office of Frank, Haron, Weiner, and Navarro as a whistleblower in 2010, just prior to what I had believed was the statute of limitations for me having learned what I had learned about UESWL. It was a decision wrought with angst and a very high degree of stress. After having worked on many important initiatives within urology since 1986, when I was no longer able to sleep after learning about the cover-up of very serious safety problems with use of *UESWL – Urinary Extracorporeal Shockwave Lithotripsy* used to treat kidney stones, I

made the extremely difficult decision to disclose this problem that was so massive it could get me murdered. I learned that the motives for this cover-up were mass-scale, multi-billion dollar kickbacks paid to urologists for referring their patients for UESWL treatment in highly sophisticated, carefully crafted cooperative "non-provider ownership" business schemes designed entirely to avert scrutiny by the Stark II and Anti-kickback laws, and were compelled using highly paid attorneys and lobbyists to assert the legitimacy of these so-called "business" schemes to legislators.

I believe it is important for you to understand some of the specifics of my case in order to evaluate my request for investigation, because I am specifically asserting my *qui tam* complaint was executed and constructed by my attorneys to ***not*** reflect the most critical information concerning the intentional and highly organized cover-up of safety issues which adversely affect the patients treated with UESWL without their distinct consent.

The urologists, along with all those other stakeholders listed in my complaint as Defendants within the schematic kickback continuum's process chose to conceal rather than disclose extremely harmful safety problems with UESWL in what I assert to be truly criminal deception for ignoring, neglecting, and intentionally concealing them at the expense of their patients' health and lives. They did this by not informing their patients, by not informing the FDA, and by highly deceptive and therefore fraudulent accounts of UESWL published in the medical literature used to protect the scheme. I witnessed the use of UESWL and heard accounts of using UESWL that were not only very dangerous, but for patently unwarranted and unethical treatments – all for the money. For instance, patients were called back for retreatments when only one treatment was truly necessary, patients who had already passed very small kidney stones on their own were treated, and patients with no visible kidney stones were treated. Patients died, required nephrectomies or splenectomies, had to endure stomach reconstruction due to damage, required blood transfusions and emergency surgeries when arteries were hit, and became diabetic when the shockwaves damaged fragile but critically functional islet cells within the pancreas. None of this was ever reported to the FDA. It has been carefully concealed for thirty long years. But my attorneys asserted (Mr. Szura in countless communications with me) that I had no legal standing to come forward with this information in my complaint. I believe I did in fact have legal standing and what Mr. Szura told me was untrue. I believe this now especially because of specific actions and responses to my filings with the FDA and with the MDCH CON Commission following dismissal of my complaint.

It was very questionable to begin to account for the massive influx of patients undergoing this traumatic UESWL procedure once the urologists had financial incentives in the scheme. Almost overnight kidney stone patients would just seem to come out of nowhere. In the medical literature it has been described that UESWL is a "non-clinical" preference. I take this to mean they choose to use it for no proper clinical reason. It is in fact used improperly and as a cover-up, permitting "medical" judgment be made nearly entirely to enhance income – it is not a "clinical" judgment made in patients' best interests or with patients' properly informed consent. As I saw it, the money was just the money – urologists and their co-conspirators were lining their pockets in a multibillion

dollar scheme. I see money as money – the problem for me was the grave and deadly harm they were concealing within a powerful and large circle of influence. Concealing the danger *for the money* was the problem to me. The extortion alone was bad enough, but the crime here is the Defendants concealing the danger from the public and the astronomical costs associated with concealment. If they were just extorting money it would be one thing, but they are endangering lives without any reasonable, truthful, public disclosure at all. My entire assertion was that the money concealed the real crime.

My attorneys crafted my complaint without accounting for the Defendants' concealing and intentionally disguising the safety problems. I don't know who of the three, Navarro, Szura, or Nolan decided this, or if it was a consensus amongst them. Very early on and throughout the process, Mr. Szura told me over and over again that I did not have legal "standing" to assert the complaint about the safety problems with UESWL. This did not make sense to me. What made sense to me was that when there were huge financial gains at stake, it is not rocket science to see why these Defendants would conceal the serious safety problems. Moreover, this was the entire basis for me complaining in the first place – the Defendants were lining their pockets, had created a whole nationalized "crime family" in order to pull it off, and they did it by endangering their patients. They have been doing this within a massive culture of corruption within urology perpetrated within a carefully crafted national front based on intentional public deceit. I didn't think it was rocket science to understand this.

I specifically believe that I must have had legal "standing", knowing now what I know about other similar cases, and this is precisely why I am requesting this investigation of my attorneys by the AGCMI. Highly skilled craftsmen - urologists, lawyers, hospital administrators, and businessmen, structured kickbacks for urologists to appear legal all the while covering up horrific dangers to people's lives in unfathomable ways.

Mr. Szura told me over and over that I would only have "*legal standing*" in a complaint had I been one to have been harmed as a result of being treated with UESWL. I do not believe this is or was true. I believe that patients harmed by UESWL did not have any natural way of knowing, or even questioning, why serious medical problems such as diabetes, hypertension, renal failure, arrhythmias, declining renal function, etc., etc., etc., happened following their treatment with UESWL. It very well may have been that when these medical problems became apparent they would have no reason to consult back with the urologist who treated them with UESWL. Without medical knowledge, these patients were left in the dark, and certainly their urologists were not interested in following them up to discover these horrific adverse effects. I felt responsible to shine a disinfecting light on these very deadly problems. Millions of patients over the last thirty years may easily have been adversely affected. And I knew that the urologists not only knew, but were afraid to reveal the problem, so they doubled down and chose their "business" schemes instead. Any patient without a medical background would have no way of knowing – they actually trust their doctors *NOT* to engage in criminal deception concerning their care.

This past week on the news I watched how a Congressional Committee grilled and drilled the new CEO of General Motors, Mary Barra, about how thirteen people died because of an ignition defect in the Chevy Cobalt that had been disguised and covered up prior to her appointment, for a purported $0.50 savings per car. This made me crazy. How is it that as a whistleblower I did not have standing to come forward with serious information about damaging UESWL safety problems and a massive cover-up affecting hundreds of thousands of innocent victims so that urologists could extort billions of dollars from the healthcare system. This is what I want to know. Thirteen casualties get a Congressional Committee, and hundreds of thousands warrant no concern? Really? How is it that I did not have legal standing to reveal this? I do not believe for one minute that our laws intend this to be true. I believe my attorneys did not represent my claims properly, and because of this, it injured me, devastated me for having stood up, and countless others who remain in the dark. This has clearly adversely affected the outcome of my *qui tam* complaint and sincere effort to properly advise proper authorities in ways that have prejudiced my claims and rights as a whistleblower. It has permitted the substantial and serious patient harm to continue unchallenged.

In summary, to the best of my knowledge, Ms. Navarro participated on the team of Navarro, Szura, and Nolan within the firm of Frank, Haron, Weiner, and Navarro at least in part by overseeing and contributing knowledge and advice concerning drafting and executing my complaint. I spoke only on occasion with Ms. Navarro, but understood that she participated in a senior role concerning my complaint behind the scenes. Both Ms. Navarro and Mr. Szura accompanied me on February 16, 2011 to the Detroit office of the U.S. Department of Justice to meet with officials concerning my complaint. Because I remained committed to exposing the safety problems regardless of my attorneys explaining that I did not have "legal standing," I was told by Mr. Szura that I would have an opportunity to explain the safety concerns not written into my complaint to the officials at that time. Mr. Szura and Ms. Navarro explained to me that discussing these safety concerns would enhance their interest in pursuing my complaint. Unfortunately, this never happened in that room when time ran out before some of the officials needed to catch planes. Ms. Navarro in my estimation is a lovely person.

In July 2013, after exhaustively seeking new legal representation following Mr. Szura forcing "voluntary" dismissal of my qui tam complaint, I decided to complain directly to the FDA because of my abject fear that allowing the continued concealment of the UESWL safety problems would just continue to wreak horrific havoc in people's lives without any intervention. The FDA ***is*** extremely concerned about my complaint for very good reason, and has undertaken a very serious investigation (Complaint File #CDRH CPT 1300384). I believe this serves to support my belief that I did in fact have legal standing to report the cover-up of the serious UESWL safety problems within my *qui tam* complaint.

Very soon after I was forced by Mr. Szura to "voluntarily" dismiss my case, the law practice of Frank, Haron, Weiner, et al ceased to exist, and these three attorneys by what I can surmise began practicing law elsewhere within Michigan. I do not know for what

reasons, but perhaps there were many other issues or pressures on my attorneys for reasons unbeknownst to me during that time. I have no way of knowing how or if this may have affected their treatment of me or my case.

Thank you for your sincere concern of my request. I need you to know that I do not have some vendetta or wish or seek any harm for Ms. Nolan, Ms. Navarro, or Mr. Szura. I need to know what happened, and only seek justice. I need to know specifically whether or not I had "legal standing" to report serious safety problems and the intentional cover-up of harm from UESWL in a whistleblower complaint. I want absolute assurance that my complaint was treated with the seriousness and care that was necessary. I kicked the beehive in order to send all the busy little bees out into the sunlight where we could see them. I have clearly been the only one stung, here. I need to know where this legal system failed me so horrifically and by association all those others I have intended to help. You may reach me at any time with questions at (708) 763-0501 or email at ae_mitchell@comcast.net.

Again, thank you.

Sincerely,

Anne Mitchell
Ae_mitchell@comcast.net
(708) 763-0501

STATE OF MICHIGAN

ATTORNEY GRIEVANCE COMMISSION

BUHL BUILDING
535 GRISWOLD, SUITE 1700
DETROIT, MICHIGAN 48226
TELEPHONE (313) 961-6585
WWW.AGCMI.COM

June 11, 2014

PERSONAL AND CONFIDENTIAL
Ms. Anne E. Mitchell
P.O. Box 3249
Oak Park, IL 60303

RE: Anne E. Mitchell as to Louis Szura
AGC File No. 1037-14

Dear Ms. Mitchell:

This office received your Request for Investigation, however, the allegations in your complaint are insufficient to warrant review by the Commission. Accordingly, after careful review by the staff. this matter is being closed under the authority of the Grievance Administrator pursuant to Michigan Court Rule 9.112 (C)(1) (a).

The Attorney Grievance Commission is not authorized to perform what is essentially a judicial function. We have evaluated each of your allegations and have determined that they do not involve a violation of the court rules enforced by this office. If you believe that your attorney engaged in legal malpractice, or gave you poor advice, you have the opportunity to bring the matter to the attention of the court. However, failure to achieve a result which you would term successful is not, by itself, evidence of misconduct. The disciplinary system is not designed to act as a substitute for your judicial or appellate remedies.

Mr. Szura has been provided with a copy of your Request for Investigation. If my staff or I can be of service to you in the future, please do not hesitate to contact us again.

Very truly yours,

Ruthann Stevens
Senior Associate Counsel

RS/de
cc: Louis Szura
Enclosure

{Reject-R4RI.doc}

Anne Mitchell
PO Box 3249
Oak Park, IL 60303
April 7, 2014

Michigan Attorney Grievance Commission
Attn: Ms. Ruthann Stevens, esq.
Complaint Intake
243 West Congress, Suite 256
Detroit, MI 48226-3259

RE: Request for Investigation of Attorney **Louis C. Szura** in: *United States of America, The States of Illinois, Indiana, Michigan, ex rel Anne Mitchell v. United Medical Systems (DE), et al. In the United States District Court for the Eastern District of Michigan Case No. 11-10090 (formerly Case No. 10C-6793 in N.D. Illinois)*

Dear Ms. Stevens and AGCMI:

To better formulate my *Request for Investigation* according to your process as you described in your letters to me of March 25, 2014 and April 1, 2014, I hereby submit the following to you.

You are aware that I have a substantial amount of documentation concerning my assertions about my complaint, since I had originally submitted this in my first attempt at filing my request with your office. At this time I shall not overwhelm you with these, but know that they are available to you as you see fit.

In 2010, I contracted with the offices of Frank, Haron, Weiner, and Navarro, 5435 Corporate Drive, Suite 225, Troy, MI 48098-2624 to represent me in the complaint mentioned above. A team from within their law practice comprised as I am aware of Susan D. Nolan, Louis C. Szura, and Monica P. Navarro worked together on my complaint, and at times I communicated directly with each of them individually and together.

I want to be clear that I liked these attorneys very much – all of them. But I do not believe that in the end they represented me and my complaint as I had clearly asserted or as I had clearly intended. I firmly believe they misinformed me concerning my legal standing in the complaint, and the resulting injury to me and to all those I had intended to inform by my actions as an informant/whistleblower is grave and substantial. I believe by my attorneys mishandling my complaint it in this manner or in manners not known to me, my *qui tam* complaint was forced to dismissal. It potentially may have come of haste or lapses in proper legal judgment. It is also possible that something sinister may have happened when Thomas E. Zeno, the thirty-year veteran and Head of the Healthcare Fraud Division of the US DOJ left to work for Defendants in my case under employ by the firm *Squires Sanders* while my case was being investigated in his Washington, DC

office for at least four months. It is for this reason I am requesting action by your Commission. *Something* went terribly wrong.

Mr. Szura was my principal point of contact during and throughout the process from development of the case to his final demand that I "voluntarily" dismiss the case. It was my belief that Ms. Navarro oversaw activities, provided guidance, and interjected her knowledge and opinions about my case as the senior partner in the firm. It is my belief that Ms. Nolan acted as a subject matter expert, researched my complaint, and worked tirelessly drafting my complaint for submission. I do not know who of the three was responsible for decisions concerning my complaint. I don't know who of them decided I did not have "legal standing" to disclose the serious cover-up scheme of the dangerous patient safety issues related to *Urinary Extracorporeal Shockwave Lithotripsy (UESWL)* within my qui tam complaint.

Ms. Navarro was recommended to me by Mr. Patrick Burns from the organization *Taxpayer's Against Fraud* in Washington, DC, first when I was seeking a specialized *qui tam* attorney. He had also given me the names of two other attorneys, but I contacted Ms. Navarro first, spoke with her at length first on the phone before she invited me to the office of Frank, Haron, Weiner, and Navarro to meet with her, Mr. Szura, and Ms. Nolan. Though I did speak with the other *TAF* recommended attorneys prior to contracting with Ms. Navarro's firm, I believed that Ms. Navarro had a far better handle on understanding my complaint than the others. After I'd met with them at their Troy, Michigan office, I do not know with any certainty what role Ms. Navarro played or continued to play in my case other than as a senior advisor or firm partner. I chose their firm because of her and the initial communications I had with her specifically believing that they were best suited and knowledgeable to prosecute my case. During the time following their remission of my complaint to the court, the firm first called "*Frank, Haron, Weiner, and Navarro*" became "*Frank, Haron, Weiner*" without the "*Navarro*." I don't know why this happened, but it was my distinct understanding that Ms. Navarro remained "*of counsel*" for the firm and did remain an active participant in my *qui tam* complaint until I was forced to "voluntarily" dismiss the case. Nearly all of my communications, mostly phone conversations after that initial meeting in Troy were with Louis Szura. It appeared that the firm had assigned him to be my primary contact and the "front-man" in communications with the U.S. Department of Justice before and after my complaint was re-assigned to the U.S. District Court in the Eastern District of Michigan from N.D. Illinois.

When my case was written and submitted first to the N.D. of Illinois, I reviewed the copy of the redacted copy and a copy prior to its submission to the court. After seeing it and realizing that cover-up of the safety problems with UESWL were not defined within the document I was alarmed. Upon discussing this with **Mr. Szura**, he explained that I did not have "legal standing" to reveal the safety problems under the whistleblower laws, but would have "standing" were I to have been a patient harmed by the procedure. I found that very troubling, because the principal reason I blew the whistle was to expose the highly sophisticated scheme in which safety problems were covered up. I expressed this

to Mr. Szura, but he reasserted that the law did not offer me whistleblower protection for revealing cover-up of the safety problems. Prior to leaving my employer, I had already once attempted to disclose these safety problems to an officer at Blue Cross/Blue Shield of Michigan, without success. I sought legal protection so that I could come forward to appropriate authorities concerning this cover-up and the kickbacks motivating it. Unfortunately, I had no recourse other than trust in the legal knowledge, experience, and advice of my attorneys about a process that was already well under way. Again, I cannot say for certain whom amongst them decided that I did not have standing to report the safety problems, but Mr. Szura was the attorney communicating this directly to me.

Throughout the process over two years I continued to question Mr. Szura about why I did not have "standing" to reveal the information that would protect consumers from the harm I knew they were being subjected to without their knowledge or consent. Mr. Szura said to me in phone conversations that the U.S. D.O.J. did not "practice medicine," and that they would never go after the urologists for "practicing medicine." I was having a distinctly difficult time understanding this when I had observed in the news, for instance, doctors charged with unnecessary surgeries, or for paying patients to perform unnecessary surgeries on them for the reimbursements they would get from the patient's insurance. I had a very hard time reconciling what I knew and had communicated as having been substantively different than those other schemes. When the patients would have no way of knowing that what was happening to them was dangerous, were not informed of the specific and prevalent dangers, were sold only on the "effectiveness" of the UESWL, were not properly offered alternatives to the kickback-motivated procedure, they would have no other means to make highly consequential medical decisions about their health and their lives. If I did not step forward with this information concerning the specific dangers, then it would remain concealed as intended by the highly organized scheme. I was an "insider." I learned what was happening to these patients long after the urologists already knew. The costs to life and treasure are gargantuan, all so that the urologists can make a few extra billion by hiding behind a fraudulently crafted so-called "business" scheme. It is insane. And it cannot be legal.

I had "standing" after all – it simply cannot be otherwise. I cannot believe that our whistleblower laws do not include protection for coming forward with information about covering up a procedure that is unsafe.

Mr. Szura explained to me that his point of contact with the U.S. D.O.J. was the AUSA named David Finkelstein out of the Washington, DC office. Mr. Finkelstein was one of the attorneys present in the one meeting I had together with my attorneys in Detroit with the AUSAs, OIG, and FBI. I have no way of knowing what conversations the two of them had, but I had continued to express to **Mr. Szura** that I needed to make sure Mr. Finkelstein understood the issues concerning the safety problems with the procedure. I don't know what **Mr. Szura** and Mr. Finkelstein discussed in reality. I do not know what the relationship was between Mr. Finkelstein and Mr. Thomas E. Zeno working together at the U.S. D.O.J. other than Mr. Finkelstein being dramatically junior and Mr. Zeno being dramatically senior within the agency. Not knowing this became even that much

more troubling to me when I'd learned from **Mr. Szura** that the U.S. D.O.J. was declining involvement in the case. None of this made sense to me.

It is my understanding from phone conversations with both Mr. Szura and Ms. Navarro that Susan Nolan worked very hard on researching and drafting the complaint itself, and that is the extent of my knowledge of Ms. Nolan's participation. However, I am unaware precisely of how it was decided and who decided to develop, draft, and execute my complaint in the manner in which it was done. I do not know how each of the members of this team participated behind the scenes in the decisions that had to have been made to execute my complaint in the manner in which they decided it was to be drafted and executed.

I stood forward by seeking legal counsel's protection from the law office of Frank, Haron, Weiner, and Navarro as a whistleblower in 2010, just prior to what I had believed was the statute of limitations for me having learned what I had learned about UESWL. It was a decision wrought with angst and a very high degree of stress. Two years later I was diagnosed with cancer without health insurance. After a very successful career and having worked on many important initiatives within urology since 1986, when I was no longer able to sleep after learning about the cover-up of very serious safety problems with use of *UESWL – Urinary Extracorporeal Shockwave Lithotripsy* used to treat kidney stones, I made the extremely difficult decision to disclose this problem that was so massive it could get me murdered. I learned that the motives for this cover-up were mass-scale, multi-billion dollar kickbacks paid to urologists for referring their patients for UESWL treatment in highly sophisticated, carefully crafted cooperative "non-provider ownership" business schemes designed entirely to avert scrutiny by the Stark II and Anti-kickback laws, and were compelled using highly paid attorneys and lobbyists to assert the legitimacy of these so-called "business" schemes to legislators.

I believe it is important for you to understand some of the specifics of my case in order to evaluate my request for investigation, because I am specifically asserting my *qui tam* complaint was executed and constructed by my attorneys to ***not*** reflect the most critical information concerning the intentional and highly organized cover-up of safety issues which adversely affect the patients treated with UESWL without their distinct consent.

The urologists, along with all those other stakeholders listed in my complaint as Defendants within the schematic kickback continuum's process chose to conceal rather than disclose extremely harmful safety problems with UESWL in what I assert to be truly criminal deception for ignoring, neglecting, and intentionally concealing them at the expense of their patients' health and lives. They did this by not informing their patients, by not informing the FDA, and by highly deceptive and therefore fraudulent accounts of UESWL published in the medical literature used to protect the scheme. I witnessed the use of UESWL and heard accounts of using UESWL that were not only very dangerous, but for patently unwarranted and unethical treatments – all for the money. For instance, patients were called back for retreatments when only one treatment was truly necessary, patients who had already passed very small kidney stones on their own were treated, and

patients with no visible kidney stones were treated. Patients died, required nephrectomies or splenectomies, had to endure stomach reconstruction due to damage, required blood transfusions and emergency surgeries when arteries were hit, and became diabetic when the shockwaves damaged fragile but critically functional islet cells within the pancreas. None of this was ever reported to the FDA. It has been carefully concealed for thirty long years. But my attorneys asserted (Mr. Szura in countless communications with me) that I had no legal standing to come forward with this information in my complaint. I believe I did in fact have legal standing and what Mr. Szura told me was untrue. I believe this now especially because of specific actions and responses to my filings with the FDA and with the MDCH CON Commission following dismissal of my complaint.

It was very questionable to begin to account for the massive influx of patients undergoing this traumatic UESWL procedure once the urologists had financial incentives in the scheme. Almost overnight kidney stone patients would just seem to come out of nowhere. In the medical literature it has been described that UESWL is a "non-clinical" preference. I take this to mean they choose to use it for no proper clinical reason. It is in fact used improperly and as a cover-up, permitting "medical" judgment be made nearly entirely to enhance income – it is not a "clinical" judgment made in patients' best interests or with patients' properly informed consent. As I saw it, the money was just the money – urologists and their co-conspirators were lining their pockets in a multibillion dollar scheme. I see money as money – the problem for me was the grave and deadly harm they were concealing within a powerful and large circle of influence. Concealing the danger *for the money* was the problem to me. The extortion alone was bad enough, but the crime here is the Defendants concealing the danger from the public and the astronomical costs associated with concealment. If they were just extorting money it would be one thing, but they are endangering lives without any reasonable, truthful, public disclosure at all. My entire assertion was that the money concealed the real crime.

My attorneys crafted my complaint without accounting for the Defendants' concealing and intentionally disguising the safety problems. I don't know who of the three, Navarro, Szura, or Nolan decided this, or if it was a consensus amongst them. Very early on and throughout the process, Mr. Szura told me over and over again that I did not have legal "standing" to assert the complaint about the safety problems with UESWL. This did not make sense to me. What made sense to me was that when there were huge financial gains at stake, it is not rocket science to see why these Defendants would conceal the serious safety problems. Moreover, this was the entire basis for me complaining in the first place – the Defendants were lining their pockets, had created a whole nationalized "crime family" in order to pull it off, and they did it by endangering their patients. They have been doing this within a massive culture of corruption within urology perpetrated within a carefully crafted national front based on intentional public deceit. I didn't think it was rocket science to understand this.

I specifically believe that I must have had legal "standing", knowing now what I know about other similar cases, and this is precisely why I am requesting this investigation of my attorneys by the AGCMI. Highly skilled craftsmen - urologists, lawyers, hospital

administrators, and businessmen, structured kickbacks for urologists to appear legal all the while covering up horrific dangers to people's lives in unfathomable ways.

Mr. Szura told me over and over that I would only have "*legal standing*" in a complaint had I been one to have been harmed as a result of being treated with UESWL. I do not believe this is or was true. I believe that patients harmed by UESWL did not have any natural way of knowing, or even questioning, why serious medical problems such as diabetes, hypertension, renal failure, arrhythmias, declining renal function, etc., etc., etc., happened following their treatment with UESWL. It very well may have been that when these medical problems became apparent they would have no reason to consult back with the urologist who treated them with UESWL. Without medical knowledge, these patients were left in the dark, and certainly their urologists were not interested in following them up to discover these horrific adverse effects. I felt responsible to shine a disinfecting light on these very deadly problems. Millions of patients over the last thirty years may easily have been adversely affected. And I knew that the urologists not only knew, but were afraid to reveal the problem, so they doubled down and chose their "business" schemes instead. Any patient without a medical background would have no way of knowing – they actually trust their doctors *NOT* to engage in criminal deception concerning their care.

This past week on the news I watched how a Congressional Committee grilled and drilled the new CEO of General Motors, Mary Barra, about how thirteen people died because of an ignition defect in the Chevy Cobalt that had been disguised and covered up prior to her appointment, for a purported $0.50 savings per car. This made me crazy. How is it that as a whistleblower I did not have standing to come forward with serious information about damaging UESWL safety problems and a massive cover-up affecting hundreds of thousands of innocent victims so that urologists could extort billions of dollars from the healthcare system. This is what I want to know. Thirteen casualties get a Congressional Committee, and hundreds of thousands warrant no concern? Really? How is it that I did not have legal standing to reveal this? I do not believe for one minute that our laws intend this to be true. I believe my attorneys did not represent my claims properly, and because of this, it injured me, devastated me for having stood up, and countless others who remain in the dark. This has clearly adversely affected the outcome of my *qui tam* complaint and sincere effort to properly advise proper authorities in ways that have prejudiced my claims and rights as a whistleblower. It has permitted the substantial and serious patient harm to continue unchallenged.

In summary, to the best of my knowledge, Ms. Navarro participated on the team of Navarro, Szura, and Nolan within the firm of Frank, Haron, Weiner, and Navarro at least in part by overseeing and contributing knowledge and advice concerning drafting and executing my complaint. I spoke only on occasion with Ms. Navarro, but understood that she participated in a senior role concerning my complaint behind the scenes. Both Ms. Navarro and Mr. Szura accompanied me on February 16, 2011 to the Detroit office of the U.S. Department of Justice to meet with officials concerning my complaint. Because I remained committed to exposing the safety problems regardless of my attorneys

explaining that I did not have "legal standing," I was told by Mr. Szura that I would have an opportunity to explain the safety concerns not written into my complaint to the officials at that time. Mr. Szura and Ms. Navarro explained to me that discussing these safety concerns would enhance their interest in pursuing my complaint. Unfortunately, this never happened in that room when time ran out before some of the officials needed to catch planes. Mr. Szura in my estimation is a lovely man.

In July 2013, after exhaustively seeking new legal representation following Mr. Szura forcing "voluntary" dismissal of my qui tam complaint, I decided to complain directly to the FDA because of my abject fear that allowing the continued concealment of the UESWL safety problems would just continue to wreak horrific havoc in people's lives without any intervention. The FDA ***is*** extremely concerned about my complaint for very good reason, and has undertaken a very serious investigation (Complaint File #CDRH CPT 1300384). I believe this serves to support my belief that I did in fact have legal standing to report the cover-up of the serious UESWL safety problems within my *qui tam* complaint. Additionally, in 2013 I provided public testimony in person and in writing to the *Michigan Department of Community Health's Certificate of Need Commission* concerning the UESWL safety problems in order to get this information out in public record. It is after this that the cockroaches all began to scurry for cover, and I have plenty of evidence of this.

Very soon after I was forced by Mr. Szura to "voluntarily" dismiss my case, the law practice of Frank, Haron, Weiner, et al ceased to exist, and these three attorneys by what I can surmise began practicing law elsewhere within Michigan. I do not know for what reasons, but perhaps there were many other issues or pressures on my attorneys for reasons unbeknownst to me during that time. I have no way of knowing how or if this may have affected their treatment of me or my case.

Thank you for your sincere concern of my request. I need you to know that I do not have some vendetta or wish or seek any harm for Ms. Nolan, Ms. Navarro, or Mr. Szura. I need to know what happened, and only seek justice. I need to know specifically whether or not I had "legal standing" to report serious safety problems and the intentional cover-up of harm from UESWL in a whistleblower complaint. I want absolute assurance that my complaint was treated with the seriousness and care that was necessary. I kicked the beehive in order to send all the busy little bees out into the sunlight where we could see them. I have clearly been the only one stung, here. I need to know where this legal system failed me so horrifically and by association all those others I have intended to help. You may reach me at any time with questions at (708) 763-0501 or email at ae_mitchell@comcast.net.

Again, thank you.

Sincerely,

11-CV-10090

HON VICTORIA ROBERTS

Anne Mitchell
Ae_mitchell@comcast.net
(708) 763-0501

STATE OF MICHIGAN

ATTORNEY GRIEVANCE COMMISSION

BUHL BUILDING
535 GRISWOLD, SUITE 1700
DETROIT, MICHIGAN 48226
TELEPHONE (313) 961-6585
WWW.AGCMI.COM

June 11, 2014

PERSONAL AND CONFIDENTIAL
Ms. Anne E. Mitchell
P.O. Box 3249
Oak Park, IL 60303

RE: Anne E. Mitchell as to Suzanne D. Nolan
AGC File No. 1038-14

Dear Ms. Mitchell:

This office received your Request for Investigation, however, the allegations in your complaint are insufficient to warrant review by the Commission. Accordingly, after careful review by the staff, this matter is being closed under the authority of the Grievance Administrator pursuant to Michigan Court Rule 9.112 (C)(1) (a).

The Attorney Grievance Commission is not authorized to perform what is essentially a judicial function. We have evaluated each of your allegations and have determined that they do not involve a violation of the court rules enforced by this office. If you believe that your attorney engaged in legal malpractice, or gave you poor advice, you have the opportunity to bring the matter to the attention of the court. However, failure to achieve a result which you would term successful is not, by itself, evidence of misconduct. The disciplinary system is not designed to act as a substitute for your judicial or appellate remedies.

Ms. Nolan has been provided with a copy of your Request for Investigation. If my staff or I can be of service to you in the future, please do not hesitate to contact us again.

Very truly yours,

Ruthann Stevens
Senior Associate Counsel

RS/de
cc: Suzanne D. Nolan
Enclosure

11-CV-10090
HON VICTORIA ROBERTS

000017

{Reject-R4RI.doc}

Anne Mitchell
PO Box 3249
Oak Park, IL 60303
April 7, 2014

Michigan Attorney Grievance Commission
Attn: Ms. Ruthann Stevens, esq.
Complaint Intake
243 West Congress, Suite 256
Detroit, MI 48226-3259

RE: Request for Investigation of Attorney **Susan D. Nolan** in: *United States of America, The States of Illinois, Indiana, Michigan, ex rel Anne Mitchell v. United Medical Systems (DE), et al. In the United States District Court for the Eastern District of Michigan Case No. 11-10090 (formerly Case No. 10C-6793 in N.D. Illinois)*

Dear Ms. Stevens and AGCMI:

To better formulate my *Request for Investigation* according to your process as you described in your letters to me of March 25, 2014 and April 1, 2014, I hereby submit the following to you.

You are aware that I have a substantial amount of documentation concerning my assertions about my complaint, since I had originally submitted this in my first attempt at filing my request with your office. At this time I shall not overwhelm you with these, but know that they are available to you as you see fit.

In 2010, I contracted with the offices of Frank, Haron, Weiner, and Navarro, 5435 Corporate Drive, Suite 225, Troy, MI 48098-2624 to represent me in the complaint mentioned above. A team from within their law practice comprised as I am aware of Susan D. Nolan, Louis C. Szura, and Monica P. Navarro worked together on my complaint, and at times I communicated directly with each of them individually and together.

I want to be clear that I liked these attorneys very much – all of them. But I do not believe that in the end they represented me and my complaint as I had clearly asserted or as I had clearly intended. They misinformed me concerning my legal standing in the complaint, and the resulting injury to me and to all those I had intended to inform by my actions as an informant/whistleblower is grave and substantial. I believe by my attorneys mishandling my complaint it in this manner or in manners not known to me, my qui tam complaint was forced to dismissal. It is also possible that something sinister may have happened when Thomas E. Zeno, the thirty-year veteran and Head of the Healthcare Fraud division of the US DOJ left to work for Defendants under employ by the firm *Squires Sanders* while my case was being investigated in his Washington, DC office. It is for this reason I am requesting action by your Commission. *Something* went terribly wrong.

Mr. Szura was my principal point of contact during and throughout the process from development of the case to his final demand that I "voluntarily" dismiss the case. It was my belief that Ms. Navarro oversaw activities and interjected her knowledge and opinions about my case as the senior partner in the firm. It is my belief that Ms. Nolan acted as a subject matter expert, researched my complaint, and worked tirelessly drafting my complaint for submission. I do not know who of the three was responsible for decisions concerning my complaint. I don't know who of them decided I did not have "legal standing" to disclose the serious cover-up scheme of the dangerous patient safety issues related to *Urinary Extracorporeal Shockwave Lithotripsy (UESWL)* within my qui tam complaint.

It is my understanding from phone conversations with both Mr. Szura and Ms. Navarro that **Susan Nolan** worked very hard on researching and drafting the complaint itself, and that is the extent of my knowledge of Ms. Nolan's participation. However, I am unaware precisely of how it was decided and who decided to develop, draft, and execute my complaint in the manner in which it was done. I do not know how each of the members of this team participated behind the scenes in the decisions that had to have been made to execute my complaint in the manner in which they decided it was to be drafted and executed.

I stood forward by seeking legal counsel's protection from the law office of Frank, Haron, Weiner, and Navarro as a whistleblower in 2010, just prior to what I had believed was the statute of limitations for me having learned what I had learned about UESWL. It was a decision wrought with angst and a very high degree of stress. After having worked on many important initiatives within urology since 1986, when I was no longer able to sleep after learning about the cover-up of very serious safety problems with use of *UESWL – Urinary Extracorporeal Shockwave Lithotripsy* used to treat kidney stones, I made the extremely difficult decision to disclose this problem that was so massive it could get me murdered. I learned that the motives for this cover-up were mass-scale, multi-billion dollar kickbacks paid to urologists for referring their patients for UESWL treatment in highly sophisticated, carefully crafted cooperative "non-provider ownership" business schemes designed entirely to avert scrutiny by the Stark II and Anti-kickback laws, and were compelled using highly paid attorneys and lobbyists to assert the legitimacy of these so-called "business" schemes to legislators.

I believe it is important for you to understand some of the specifics of my case in order to evaluate my request for investigation, because I am specifically asserting my qui tam complaint was executed and constructed by my attorneys to ***not*** reflect the most critical information concerning intentional and highly organized cover-up of safety issues which adversely affect the patients treated with UESWL.

The urologists, along with all those other stakeholders listed in my complaint as Defendants within the schematic kickback continuum's process chose to conceal rather than disclose extremely harmful safety problems with UESWL in what I assert to be truly criminal deception for ignoring, neglecting, and intentionally concealing them at the

expense of their patients' health and lives. They did this by not informing their patients, by not informing the FDA, and by highly deceptive and therefore fraudulent accounts of UESWL published in the medical literature used to protect the scheme. I witnessed the use of UESWL and heard accounts of using UESWL that were not only very dangerous, but for patently unwarranted and unethical treatments – all for the money. For instance, patients were called back for retreatments when only one treatment was truly necessary, patients who had already passed very small kidney stones on their own were treated, and patients with no visible kidney stones were treated. Patients died, required nephrectomies or splenectomies, had to endure stomach reconstruction due to damage, required blood transfusions and emergency surgeries when arteries were hit, and became diabetic when the shockwaves damaged fragile but critically functional islet cells within the pancreas. None of this was ever reported to the FDA. It has been carefully concealed for thirty long years. But my attorneys asserted (Mr. Szura in countless communications with me) that I had no legal standing to come forward with this information in my complaint. I believe I did in fact have legal standing and what Mr. Szura told me was untrue. I believe this now especially because of specific actions and responses to my filings with the FDA and with the MDCH CON Commission following dismissal of my complaint.

It was very questionable to begin to account for the massive influx of patients undergoing this traumatic UESWL procedure once the urologists had financial incentives in the scheme. Almost overnight kidney stone patients would just seem to come out of nowhere. In the medical literature it has been described that UESWL is a "non-clinical" preference. I take this to mean they choose to use it for no proper clinical reason. It is in fact used improperly and as a cover-up, permitting "medical" judgment be made nearly entirely to enhance income – it is not a "clinical" judgment made in patients' best interests or with patients' properly informed consent. As I saw it, the money was just the money – urologists and their co-conspirators were lining their pockets in a multibillion dollar scheme. I see money as money – the problem for me was the grave and deadly harm they were concealing within a powerful and large circle of influence. Concealing the danger *for the money* was the problem to me. The extortion alone was bad enough, but the crime here is the Defendants concealing the danger from the public and the astronomical costs associated with concealment. If they were just extorting money it would be one thing, but they are endangering lives without any reasonable, truthful, public disclosure at all. My entire assertion was that the money concealed the real crime.

My attorneys crafted my complaint without accounting for the Defendants' concealing and intentionally disguising the safety problems. I don't know who of the three, Navarro, Szura, or Nolan decided this, or if it was a consensus amongst them. Very early on and throughout the process, Mr. Szura told me over and over again that I did not have legal "standing" to assert the complaint about the safety problems with UESWL. This did not make sense to me. What made sense to me was that when there were huge financial gains at stake, it is not rocket science to see why these Defendants would conceal the serious safety problems. Moreover, this was the entire basis for me complaining in the first place – the Defendants were lining their pockets, had created a whole nationalized "crime family" in order to pull it off, and they did it by endangering their patients. They

have been doing this within a massive culture of corruption within urology perpetrated within a carefully crafted national front based on intentional public deceit. I didn't think it was rocket science to understand this.

I specifically believe that I must have had legal "standing", knowing now what I know about other similar cases, and this is precisely why I am requesting this investigation of my attorneys by the AGCMI. Highly skilled craftsmen - urologists, lawyers, hospital administrators, and businessmen, structured kickbacks for urologists to appear legal all the while covering up horrific dangers to people's lives in unfathomable ways.

Mr. Szura told me over and over that I would only have "*legal standing*" in a complaint had I been one to have been harmed as a result of being treated with UESWL. I do not believe this is or was true. I believe that patients harmed by UESWL did not have any natural way of knowing, or even questioning, why serious medical problems such as diabetes, hypertension, renal failure, arrhythmias, declining renal function, etc., etc., etc., happened following their treatment with UESWL. It very well may have been that when these medical problems became apparent they would have no reason to consult back with the urologist who treated them with UESWL. Without medical knowledge, these patients were left in the dark, and certainly their urologists were not interested in following them up to discover these horrific adverse effects. I felt responsible to shine a disinfecting light on these very deadly problems. Millions of patients over the last thirty years may easily have been adversely affected. And I knew that the urologists not only knew, but were afraid to reveal the problem, so they doubled down and chose their "business" schemes instead. Any patient without a medical background would have no way of knowing – they actually trust their doctors *NOT* to engage in criminal deception concerning their care.

This past week on the news I watched how a Congressional Committee grilled and drilled the new CEO of General Motors, Mary Barra, about how thirteen people died because of an ignition defect in the Chevy Cobalt that had been disguised and covered up prior to her appointment, for a purported $0.50 savings per car. This made me crazy. How is it that as a whistleblower I did not have standing to come forward with serious information about damaging UESWL safety problems and a massive cover-up affecting hundreds of thousands of innocent victims so that urologists could extort billions of dollars from the healthcare system. This is what I want to know. Thirteen casualties get a Congressional Committee, and hundreds of thousands warrant no concern? Really? How is it that I did not have legal standing to reveal this? I do not believe for one minute that our laws intend this to be true. I believe my attorneys did not represent my claims properly, and because of this, it injured me, devastated me for having stood up, and countless others who remain in the dark. This has clearly adversely affected the outcome of my *qui tam* complaint and sincere effort to properly advise proper authorities in ways that have prejudiced my claims and rights as a whistleblower. It has permitted the substantial and serious patient harm to continue unchallenged.

In summary, to the best of my knowledge, Ms. Nolan participated on the team of Navarro, Szura, and Nolan within the firm of Frank, Haron, Weiner, and Navarro at least in part by researching and drafting my complaint. I rarely spoke with Ms. Nolan, but understood that she put a great deal of effort into my complaint behind the scenes. Ms. Nolan in my estimation is a lovely person.

In July 2013, after exhaustively seeking new legal representation following Mr. Szura forcing "voluntary" dismissal of my qui tam complaint, I decided to complain directly to the FDA because of my abject fear that allowing the continued concealment of the UESWL safety problems would just continue to wreak horrific havoc in people's lives without any intervention. The FDA ***is*** extremely concerned about my complaint for very good reason, and has undertaken a very serious investigation (Complaint File #CDRH CPT 1300384). I believe this serves to support my belief that I did in fact have legal standing to report the cover-up of the serious UESWL safety problems within my qui tam complaint.

Very soon after I was forced by Mr. Szura to "voluntarily" dismiss my case, the law practice of Frank, Haron, Weiner, et al ceased to exist, and these three attorneys by what I can surmise began practicing law elsewhere within Michigan. I do not know for what reasons, but perhaps there were many other issues or pressures on my attorneys for reasons unbeknownst to me during that time. I have no way of knowing how or if this may have affected their treatment of me or my case.

Thank you for your sincere concern of my request. I need you to know that I do not have some vendetta or wish or seek any harm for Ms. Nolan, Ms. Navarro, or Mr. Szura. I need to know what happened, and only seek justice. I need to know specifically whether or not I had "legal standing" to report serious safety problems and the intentional cover-up of harm from UESWL in a whistleblower complaint. I want absolute assurance that my complaint was treated with the seriousness and care that was necessary. I kicked the beehive in order to send all the busy little bees out into the sunlight where we could see them. I have clearly been the only one stung, here. I need to know where this legal system failed me so horrifically and by association all those others I have intended to help. You may reach me at any time with questions at (708) 763-0501 or email at ae_mitchell@comcast.net.

Again, thank you.

Sincerely,

Anne Mitchell
Ae_mitchell@comcast.net

000022

11:CV-10090

HON VICTORIA ROBERTS

(708) 763-0501

Anne Mitchell
P.O. Box 3249
Oak Park, IL 60303
March 15, 2014

Michigan Attorney Grievance Commission
ATTN: Complaint Intake
243 West Congress, Suite 256
Detroit, MI 48226-3259

RE: Case # U.S. E.D. Michigan (10-C-6793) (2:11-cv-10090)

Dear AGCMI:

"Blowing the Whistle" is no frivolous endeavor and involves a decision which can place one's life in serious peril. It is undertaken with very careful thought and consideration, and as with my case as an employee – a person who must work for a living, this is especially true with the impact of exposing large-scale civil and criminal activity encompassing business, government, and society. Blowing the whistle is a daunting and extremely stressful undertaking with very high risk for losing health, property, employment, support of friends and family, and even life itself. The devastating reality of what happens to the lives of whistleblowers is widely known within the American legal profession from countless accounts written by whistleblowers about their experiences. It is widely known to elicit profound instability in one's life due to an inability for a whistleblower to gain future employment.

I am requesting to learn through your agency and investigation if and how my attorneys messed up my qui tam whistleblower complaint. There are many aspects to this, including them figuring out how to manage a "constructive discharge" complaint that should have been brought to bear but was not. When I have described my complaint to highly regarded medical professionals with careers spanning hundreds of years collectively, they are baffled at how my case was handled and merely dropped and dismissed before ever going before a judge. What I learned, and what I have been able to confirm and describe to people of esteemed medical authority makes them as sick as it made me, and with that being said, when something as serious as my complaint is raised, we, the people and I in particular need answers about how such a serious complaint has gone so wrong in our legal system.

It is entirely possible that my complaint was botched in its presentation, construction, execution by my attorneys to and with the US Department of Justice. But because I am not an attorney, I need to have confirmation about what really happened with specific details, because my attorneys did not communicate this to me. When I compare my complaint to other similar successfully prosecuted complaints as I will describe later to you, it is baffling that mine was as it appears – simply tossed out by the US DOJ. Something must have been botched, or corrupted, for this to have happened, because the impact on the lives of millions of people affected by me exposing the peril of what I learned is massive and devastating. The danger and harm is far, far more in fact than in other cases similar to mine.

When contracting to represent a whistleblower, my expectations were that distinct and very carefully measured ethical considerations be weighed by my attorneys as competent professionals for ensuring my best interests as their client. As American citizens we believe and expect that our laws are there to protect us. Taking great care in constructing cases that can have such very dire consequences for the life a whistleblower is of monumental importance and necessary as a matter of justice for the person they represent who steps forward with seriously damaging information.

When entering into a contract for representing a whistleblower, it is a serious matter of enormous consequence that attorneys ***listen*** and consult carefully with a client to ensure that proper representations of a whistleblower's claims/complaints are executed in order to protect the interests of the client. There is no room for arrogance or dismissiveness by the attorneys. It is also a matter of serious enough concern if the attorneys do not understand considerable technical information provided them by their client that alone may be very germane and critical to successfully bringing the case, that they then actively and carefully seek whatever information is necessary to gain complete enough understanding, even via other reliable sources, to properly construct and execute the complaint. It is not enough to be blindly presumptive or make haughty, hasty, or poorly considered assumptions that will undermine the successful execution of the complaint.

It is a serious matter when claims are not properly considered and executed, or inadequate or deceptive legal advice is given, or misrepresentations are made to the client about the law, knowledge of the law by attorneys, or of their ability to adequately represent the client. If a case goes bad, to the client it is not just a "win-some-lose some" event as was described to me by my attorneys: "Yeah, you can just file bankruptcy, it happens all the time, and just reinvent your life." No harm, no foul, just get on with your life is how they summed it up. Sure. Fate, here, rarely has anything whatsoever to do with such a failure – ***something*** went ***wrong*** in the execution of my complaint. These attorneys know that 'win-some-lose-some" is not the reality of how it goes for a whistleblower. But it didn't really seem to matter at all to them, because my attorneys simply moved on to the next case in their massive caseload. The arrogant and cavalier attitude displayed to me by these attorneys concerning a case of such gravity, I believe, resulted in a failure to launch. This failure caused me and countless others great harm.

It is a serious matter if the attorneys envision a whistleblower's case as a "craps-shoot," just one case on their pile of cases, but do not convey it as such to the whistleblower. The decision to move forward with a case by the whistleblower is a serious matter in which carefully weighing all risks must be done, including the strength of the case, and the history of other similar cases. There is nothing whatsoever about my actual complaint that should ever have seemed like merely a roll of the dice to anyone, including my attorneys and how they represented it to the US DOJ. I would never have consented to going through what I went through if I had at any time believed that what I was exposing was not deadly serious enough to come forward. I cannot remotely imagine that what I have meant to disclose represents some small roll of the dice in exposing highly consequential, deadly medical fraud. People have died and have been and are

being badly harmed and highly deleterious information about the unproven safety of a medical device was and continues to be concealed – for the money.

It is as well a serious matter when attorneys may weigh the importance of their professional relationships with agencies such as the U.S. Department of Justice as more important than the interests of their clients. It felt very strange to me that my attorneys just rolled over when the US DOJ did not take my case, and then under extreme pressure made me sign to "voluntarily" dismiss the case. It became quite apparent to me that because the nature of their practice was qui tam cases, my attorneys needed to uphold a very supportive relationship in order to continue to have favor with the Michigan US DOJ to bring their future cases. It is also not okay and may even be deceptive and detrimental to the quality of their work when attorneys line up massive caseloads that are too much to humanly manage, especially when engaging whistleblowers whose lives hang in the balance of any poorly researched or managed aspect of a case due to potential time mismanagement critical to its successful execution. It is not okay to maintain a consistently adversarial mindset in constructing the complaint at the expense of listening clearly and carefully to what the client is explaining and demonstrating to the attorney about their claims. I do not believe that my attorneys competently executed my complaint. This may have happened for any number of reasons, but it all went seriously wrong where it shouldn't have.

I am absolutely baffled how my complaint could have been dismissed. It does not make sense.

My complaint was straightforward, but it involved a very large scale cover-up of fraud within hundreds of skillfully designed organizations, and with thousands of people within a well-orchestrated but largely concealed secret effort. I discovered an elaborate massive kickback scheme in which urologists possessed "non-provider ownership interest" in "businesses" (mostly within layers upon layers of LLC's formed for that purpose) into which they referred their patients. These "businesses" were external to their private/office practices and were secretly and successfully grown over a thirty-year time-frame to national proportion in absence of reasonable oversight by any agency permitting the careful, callous, sophisticated, and methodical cover-up of a widely used medical procedure (UESWL) that is ***unsafe***.

The most critical, salient, and relevant factor in my complaint remains today and has always been that I wanted above all to reveal those means and methods used by urologists to cover up the very dangerous and life threatening risks of UESWL technology, how patients were not and are not properly assessed for adverse effects, and how patients' lives have thereby been gravely endangered in absence of appropriate medical authority and oversight. Massive amounts of money in carefully crafted kickbacks provide the motive for this serious neglect to inform and provide safe care by these urologist business "owners." What I learned was that this is an ethical breach in trust and responsibility with clear intent by urologists that is so complete a violation in fundamental medicine ethics that it cannot be legal. Medical judgment comes with a very specific responsibility to long held principles in a well established Code of Medical Ethics. Purposely, intentionally ignoring and avoiding clear, distinct responsibility to establish the

objective, unbiased, truthful risk/benefit ratio of a procedure such as UESWL that has not been proven safe, when you have knowledge and evidence of serious harm cannot possibly be legal.

Urologists and their collaborators' absolute financial motivation has resulted in egregious misrepresentations made to patients when acquiring "patient consent" for UESWL by not truthfully representing the serious life-altering harm caused by the procedure. This has cost untold numbers of patients their good health, and some their lives. Patients were never given the opportunity to weigh the true risks and benefits of a dangerous procedure because they were misled, en masse, about the safety of UESWL. There are massive aftershock effects of these misrepresentations that take the form of outrageous costs to the healthcare system in general for treating the serious and long term adverse effects of UESWL. Granted, there is subjectivity in medicine. But when subjectivity becomes a desired exploitative means to a carefully constructed personal financial end, replacing critical objectivity that is easily obtainable through proper practice and research, then the ethical duties of those practicing the medicine are seriously breached. I believe that what these urologists are perpetrating in their carefully crafted and organized "joint ventures" are serious and grotesque human rights violations.

Without oversight, these urologists saw that no one was standing in the way of their highly deceptive enterprise, so as they continued to get away with it year after year over thirty years they became more and more emboldened and more and more clever at protecting the evidence that could if exposed otherwise deter their financial scheme. I discovered what so many other whistleblowers in past have discovered: that improper financial incentives were disguised and hidden, and that these incentives drove improper use of this specific technology. These highly successful "businesses" constrained and convoluted the obvious and necessary medical research badly needed to ensure patient safety when all the evidence pointed to it being unsafe. By protecting and concealing the truth about UESWL, urologists were able to gain patient consent for the procedure through intentional, harmful, and fraudulently deceptive means, en masse. It is easy to cover up such a serious problem as long as everyone's doing it and no one else is watching.

They simply endeavored to deceptively establish UESWL as the "standard of care." They feel entitled to their outside "business" interests because Medicare "doesn't pay." But the difference between this UESWL "standard of care" and other standards of care is the massive amount of financial kickback incentives involved, and that UESWL is harmful and distinctly unsafe. This is not some minor consideration. Disguising an unsafe medical/surgical procedure is not some minor consideration. It violates basic human rights.

The financial incentives have become so large-scale, with so many professionals involved, that it has become an art form within urology to mask the serious safety issues known about the very harmful and traumatic nature of UESWL. They now even refer in the medical literature to UESWL as a "non-clinical preference (translation: for the money)." Non-clinical? What is this supposed to mean? For more than thirty years they have not clarified the risk/benefit ratio of UESWL over alternatives. There is absolutely no safeguarding of ethics in their medical UESWL research to minimize their very serious and significant financial biases. The urologists

and their "businesses" have intentionally withheld very damaging evidence of UESWL harm from any reports to the FDA, have refused to publish valid research in the medical literature, and have mocked patient safety with deliberate hubris and deception in how they "sell" UESWL to patients. The cost to patients, the government, to insurance companies, and employers alike for this fraud is hard to calculate for this thirty year act of deception borne of their indiscriminate greed, outrageous hubris, and gross neglect of honest and proper medical judgment.

Hundreds of thousands of people over thirty years were and are continuing to be harmed in horrible ways, including death from the procedure, by not being properly informed about the seriousness of the adverse effects of UESWL. This deceptive practice is costing unnecessary hundreds of billions of healthcare dollars and unmeasurable harm. Patients have no way of knowing that what has been happening to their health directly relates to having undergone the UESWL procedure. The adverse effects from the procedure are very serious and life-altering, such as loss of kidney function, hypertension, and diabetes to name a few. If their doctors never tell them the truth about these ill effects being related to their UESWL procedure, these patients will never have the medical knowledge to connect the dots on their own.

There are distinct alternative therapies to UESWL that do not pose such adverse risks, but the urologists refuse to perform clear straightforward research they know is necessary to adequately quantify adverse effects and compare them. Ureteroscopy, for example, is described as an interchangeable alternative to UESWL, but there is no money in ureteroscopy for the urologists. Ureteroscopy is well known not to damage the kidney, and does not in any case adversely affect the pancreas, stomach, spleen, etc., as UESWL is well known to do. But, the urologists refuse to quantify these effects as a matter of disclosure in the medical literature, and therefore they do not feel responsible to have to disclose them to their patients because it would then destroy their UESWL enterprise. They would prefer their patients be harmed it appears by all accounts over telling their patients the truth. It has gone on so long now, this scheme, that the deception of it is creating a disgusting phenomenon of self-deception in the urologists themselves! The story they seem to be telling themselves at this point is that all this is perfectly okay, and they are entitled to make all this money in this manner. It is deeply, profoundly disturbing.

Therefore, to the lay patient, the adverse effects they experience as a result following UESWL treatment may seem separate, apart from their UESWL treatment. Because they are not informed of critical details of the truth by their urologists, the patients do not naturally relate the adverse effects they suffer as being attributable to UESWL. It is in the best financial interests of the doctors receiving the kickbacks through these co-ops to mislead their patients, and not properly disclose the facts of these adverse effects in order to gain consent from the patients for the procedure.

The urologists are coached in this "business scheme" how to carefully execute the obtaining of patient consent for the procedure. They focus almost entirely on how "effective" the procedure is, how "common" the procedure is, how "convenient," and how "non-invasive." They don't lie about this to their patients, but they do commit the worst possible form of lie – the lie of

omission of critical facts about the outlying dangers. And they are able to sidestep this with their patients in the signed informed consent by making the patients sign that they have had the opportunity to consider everything about the procedure and have had the opportunity to ask questions about the procedure, and that they have had all their questions answered to their satisfaction. But, the patients are given no clues whatsoever by the doctors they trust about what questions they should be asking – these patients do not possess the medical knowledge to know what types of questions are most important. They are very vulnerable and they trust these doctors!

This "sales" method is a deliberate means for sidestepping, for glossing over known grave safety hazards associated with the procedure. And when urologists set these patients up to believe that the procedure is the next best thing to sliced bread, these patients are extremely happy that their kidney stone was "pulverized" without open surgery. If you ask the patients, they "love" the procedure! But the most damaging aspect of how the urologists' "business" interests have overtaken the medical integrity of UESWL, is that they have not reported what they know to be mountains of evidence about grave adverse effects to the FDA. They know, but they have carefully constructed "protection" against the damning evidence in revealing only marginally anecdotal research in the medical literature, and in never voluntarily reporting what they know to be true to the FDA.

To honest medical professionals, you will discover when they learn of this deadly secret, with the clear and simple medical facts behind it once disclosed, makes them very sick to think about it. Over the last thirty years, the FDA has continued to approve 510K revisions for new "substantially equivalent" versions of the UESWL technology over and over and over again to the manufacturers, in absence of the critical knowledge of what this procedure/technology is actually doing to patients. The FDA has not been informed about what the urologists know. The urologists have not let them in on it.

Were UESWL instead to be a "pill" that these urologists had no financial interest in one way or another, it is far more likely they would be afraid to prescribe it for their patients, and so would likely notify the FDA about their grave concerns. They would not want to be held to account if the "pill" they prescribed caused hypertension or diabetes in their patient, or if the pill destroyed their patient's kidney function over a period of 5-10 years or so. They would deem this "pill" to be unsafe. But that is not what is happening here – they are protecting the UESWL evidence in order to protect their massive income stream from the kickbacks paid to them for their patient referrals in these co-op style "business" schemes. These urologists would likely want a pharmaceutical manufacturer to be held to account for the dangerous "pill," but they do not want the FDA to know about what is happening in their dangerous UESWL "businesses."

Again, this is an unsafe medical procedure performed within a massive kickback scheme where the FDA has abdicated responsibility to the urologists to report concerns for safety. By FDA abdicating this oversight, the urologists have had the open road, carte blanche – they have been granted authority to be ***both judge and jury*** in how they decide to address very serious known safety issues of UESWL, how they choose to inform or not inform their patients, what

research gets published, and when or if they decide to report concerns to the FDA. They have clearly chosen the ***business*** of UESWL over the ***medicine*** of UESWL. They've chosen to conceal the facts, "sell" the procedure by engaging in deceptive means to gain patient consent, and take the billions of dollars in "passive" income through their highly deceptive and carefully concealed and executed massive cooperative kickback scheme. For the money, they are endangering patients' lives without properly gaining truly informed patient consent. The deception is horrific.

The attorneys representing me, in particular Mr. Szura and Ms. Navarro, stated to me explicitly that I did not have standing in a *qui tam* whistleblower case to reveal the harm to patients caused by the UESWL procedure, or that there were very serious safety issues not being disclosed nor addressed. Mr. Szura told me that as long as the procedure had been approved by the FDA to be safe then no one could go after the doctors. I don't buy this – the doctors knew the details and had distinct responsibility to report what they knew about the seriousness of the safety issues to the FDA when the FDA may not have gotten it right in their hasty approval of UESWL technology in 1984. FDA approval alone does not exempt the doctors from their responsibilities to keep their patients safe, particularly when these doctors know a grave mistake may have been made by FDA in judging the procedure to be safe. The urologists had a distinct responsibility to know what was happening to their patients treated with UESWL and they did know. If it is true that no one will go after the doctors, then just like anyone else they should go after their businesses – unfortunately in this case the doctors and the "businesses" are the same. Go after them as business owners, then, if they're not going to go after them as doctors! Christ! Upon examining the details of FDA approval, it is crystal clear what went wrong. But the doctors did nothing and said nothing enough to raise any reasonable flags of alarm. They chose their ***business*** schemes.

Mr. Szura told me that there was nothing that could be done in the law where I would have standing. Mr. Szura told me explicitly that I would only have standing if I had personally been harmed by the procedure as a patient. Over and over again, Mr. Szura told me that I did not have standing to come forward with a claim against the myriad of safety issues of UESWL and how they were related to the kickback scheme. In other words, I was to stand idly by and just do nothing as I witnessed what harm was being done to others in this deadly scheme? Really? As I stated earlier, the patients who have been harmed by the procedure have been undermined by urologists obtaining improper patient consent for the procedure, by gross misrepresentation of the facts concerning UESWL safety. These doctors and their collaborators are essentially breaching consent contracts with their patients by being highly deceptive about how they misrepresent the safety of UESWL to them by merely omitting the facts. It is therefore nearly impossible for patients to connect the dots and know that the harm they have been caused has been attributable to UESWL! So, how on earth are these patients ever going to find out if no one tells them what the urologists know but are carefully and masterfully concealing?

I fully intended that the very point of my complaint as a whistleblower in this case was to reveal grave harm and danger to the public is being cloaked in a massive, sophisticated cover-up

scheme to assert power and extort people's healthcare dollars. I wished to expose the seriousness of this danger much in the same way as anyone who had discovered that a "pill" on the market was causing grave danger either by not disclosing safety, efficacy, or improperly marketing the "pill," but that the danger was being disguised in order to keep the money flowing. I do not see the difference in the matter of law, and will need to be convinced that this was not a very grave error by my attorneys. I simply cannot imagine that it is perfectly okay for urologist-owned enterprise to willfully conceal danger and callously ignore their patients' safety and well-being in favor of lining their pockets. Is this really true that I have no standing to report this to be a very serious crime as a whistleblower? If I don't, who exactly does have standing?

The only difference I can conceive of in my case is that at least some of the manufacturers of UESWL technology really don't know that their technology is causing such harm. The manufacturers are selling their machines into these so-called urologist-owned "business" schemes, where all the details, including harm to the patients from the operation of these UESWL machines are concealed. The manufacturers themselves are for all goods and purposes left in the dark about what is happening with their own equipment. In some cases, including with my previous employer, UMS, it is not the manufacturer going to the FDA directly, but representatives from within these urologist-ownership "businesses" that construct, for instance, the 510K approval submissions to the FDA on behalf of the manufacturers. It is the doctors themselves who are covering up the problems with the technology: they are not disclosing the problems to the manufacturers, the FDA, or their patients. Some of these operations, like "Healthtronics" however, are both manufacturer and operators of the scheme. It is within the non-provider urologist ownership schemes where the bulk of the financial incentive for this technology lies, not fully with the manufacturers. And then the hospitals they contract with simply just go along for the ride. However, this whole scenario plays out still much the same as a pharmaceutical manufacturer who may conceal the harm for the money. What precisely is the difference when harm is harm? What difference does it make whether it is a drug company or network of physician-owned LLCs contracting with hospital providers who are concealing the harm?

Attorneys Szura, Navarro, and Nolan with the firm of *Frank, Haron, Weiner, and Navarro* constructed and executed the qui tam case as enclosed with me as relator, therefore, to focus on what they represented to me as my only "standing" in the qui tam case. They constructed this qui tam case to be entirely about how the cooperatives these urologists and their collaborators constructed were permitting kickbacks to be paid them for the referral of patients in essence, and thereby engaging in False Claims against the federal government. The case they constructed on my behalf included nothing of the heart of the matter of my claim: that these improper incentives were so rich and enticing that urologists within their little side-businesses were **endangering their patients** without disclosing the facts about the safety of the procedure to anyone. But this case as my attorneys constructed it in my estimation did not represent my claims as I perceived them to reflect that doctors and their "business" partners were misleading and endangering their patients in order to create a crafty means for obtaining substantially more money. But instead, though entirely true as well, that these doctors were able to convince

hospitals to contract with them for their UESWL services by hanging patient urology referrals over the hospitals' heads. My attorneys focused entirely on the Anti-kickback and Stark II issues and not on the fraudulent misrepresentation of the UESWL procedure as being "safe." My attorneys did however represent to me that in their discussions with the US DOJ they would present the safety concerns about the procedure, and that this would be enough for the US DOJ to understand the importance of the impact of my complaint. This is very confusing to me, and doesn't seem remotely right.

I cannot reconcile that lying to the public about the safety of a medical procedure and carefully and intentionally protecting this lie is not evidence of a "False Claim" in the law, when it is especially done for the money. From everything I can ascertain, many other whistleblowers have been relators in very similar claims, and had "standing" where they revealed public danger of either devices or drugs that were being improperly represented in the marketplace as safe and/or effective! Therefore, I want to understand in very specific detail why it was that I did not have "standing," according to these attorneys, to bring my claims.

I remain completely baffled at how mine was not constructed as a case that revealed fraudulent and excessive money schemes (regardless whether or not they were devised as business entities in compliance with the exceptions within Anti-Kickback statutes) are the very reason that a very serious and substantial consumer safety problem is successfully deployed and concealed from both the public and all those others including the government who pay for these dangerous UESWL services. This is just not that complicated – hiding safety matters related to a medical procedure in order to make boatloads of money. There have been many such cases.

What if an engineer at Ford Motor Company, for instance, came forward after learning there were serious problems with brakes in cars that endangered lives but were impossible to be fixed in a certain design, and that the company continued to market and sell the cars without disclosing the defects...for the money? Wouldn't that "whistleblower" have "standing" to come forward and tell the truth to protect consumers from harm? I don't get it. I didn't get it then, and I don't get it now.

What about how *John Kopchinski* in a qui tam lawsuit against Pfizer Inc. alleged the company was engaged in the off-label marketing of *Bextra*, a painkiller, in dangerous doses and for unapproved, unsafe uses. Somehow Mr. Kopchinski had "standing." What about the case of *David Franklin v. Parke Davis*? Somehow Mr. Franklin had "standing" to enter into a qui tam case with the federal government in which the "business" withheld evidence that a drug was not effective for an off-label use and that the "company" rather continued to market the drug for unsafe and ineffective uses. Just how different is Franklin's "standing" from my "standing" for my case where I asserted that the FDA was aware they did not have critical information (including short/long-term follow-up) concerning the safety of UESWL and that the doctors within their secret kickback schemes made certain that the FDA never found out the truth when they discovered the procedure was unsafe, going to extremes to ensure that safety characteristics of UESWL were never properly addressed and patients as well were never properly informed of

the evidence? This evidence has been withheld in order to protect their massive income streams from the kickbacks, the same way any pharmaceutical manufacturer might do if they so intended.

The urologists in their UESWL schemes had full professional responsibility to report the safety issues they knew were problematic, ***especially*** if the FDA was unaware. They have not done this – ever. They manipulated the medical research. They continue to protect the harmful evidence to allow the kickbacks to continue. Both *Franklin's* and my cases from everything I can see are both clearly very serious False Claims with monumental harm exacted against healthcare consumers, insurance providers, and the government. *Mr. Kopchinski* and *Mr. Franklin* were not personally caused harm because they ingested the pharmaceuticals their employers sold and marketed. I was not personally caused harm because I underwent a UESWL procedure. There must be a very concise legal explanation for the difference, and I want to be informed of this, please, and it is for this reason I am requesting this very critical investigation of my attorneys and my case.

I am asking for a clear legal explanation about why these men had "standing" in their cases and why I did not. My life has been threatened because of this. I had the US Marshalls come pounding on my door and frightening my neighbors. I am asking to understand whether these men had "standing" because their qui tam cases were properly constructed and executed by their attorneys and whether mine may not have been properly and competently constructed and executed to reflect my claims. I want to know what impact this had on the outlandishness of how I was forced by Mr. Szura to agree to "voluntarily" dismiss the case and how my case was summarily dismissed before it ever reached the courtroom. I want to know just how it was that my qui tam case could have been in his US DOJ Department in Washington DC (though was in the court system in the E.D. of Michigan) from at least February 2011 until May 2011when Mr. Thomas E. Zeno worked there but then abruptly left and went to work for the AKSM Defendants in my case, after which he was suddenly able to secure the sudden and outlandish dismissal of my claim without anyone providing me any fair and reasonable explanation.

Additionally, I want to know: Did I not have "standing" because I was not pointing the finger at a pharmaceutical manufacturer? Is the law specific to pharmaceuticals? If that is the case I want to make damn sure that our USDOJ and DHHS are fully investigated, because pharmaceutical companies are not the only villains in medicine, and it is completely unjust not to address the full spectrum of harm caused by those who would harm, regardless whether they are pharmaceutical manufacturers, device manufacturers, doctors, or anyone else.

It has occurred to me that if my case was not thoughtfully, carefully, properly constructed and executed to reflect the specific claims I was making that this may characterize the type of professional errors by my attorneys that have likely ***prejudiced my rights and claims*** for having come forward in this case in the first place. Having been forced to dismiss the case, I quite clearly have been exposed and harmed irreparably for having blown the whistle. I have lost everything. I believe these attorneys messed up by not directly asserting my claims about the serious safety problems being hidden from patients concerning UESWL by everyone involved. Though I have been told by Mr. Szura that the US DOJ does not have to provide me any reason

whatsoever about why they demanded I "voluntarily" dismiss this case, I want answers why any of these parties would permit such crime to continue to be executed against millions of vulnerable people. There must be a very clear explanation for this. Because, when it comes to a drug like *Bextra* or *Vioxx*, there seems to have been no problem. How is *UESWL* so different? I believe my case was tossed out by the US DOJ and my attorneys because it had not been competently constructed and executed in the first place by those people I trusted to do so.

When Mr. Szura forced me to sign to dismiss the case, he also explained to me that I had ninety days to find another attorney, because he would be unable to represent me since the USDOJ had not agreed to take part. Mr. Szura also told me that it was not likely possible for me ever to find an attorney for the case if the government did not want to be involved. He was right: I have been searching for legal representation ever since and have been unable to find this. I am not an attorney, so the very fine details of the law are unknown to me – this is why we have legal professionals. However, I want to know that I have received proper professional care from the attorneys representing me. I especially want to know if they botched my case by not representing my claims as I'd asserted.

I have never been given any reasonable or adequate explanation for the reasons and was not provided any reasonable account for why this case was dismissed, but I did find information (included) on the *Squires Sanders* website in their explanation for how Mr. Zeno was able to accomplish dismissal. Because of what is being written about my case by others on the internet, it is my belief that my case was not properly executed on my behalf to exact the full depth and breadth of my claims. I just cannot imagine that the DHHS, OIG, and USDOJ would permit such a serious public safety problem to continue without intervening. More than that, I cannot abide that the public remains so seriously endangered in absence of proper warning.

After spending over a year trying to find legal representation since Mr. Szura dropped me and my case like a lead balloon, **I went to the FDA directly**. They **are** rightfully and reasonably concerned it seems, and it appears they are investigating my assertions about the safety of the procedure. However, now I suspect they may too feel threatened by my complaints about the safety and cover-up of UESWL. I believe that my qui tam case was not properly handled to protect my interests and well-being. Not only has my career and ability to provide for myself been destroyed, but THE HARM from this procedure is being allowed to continue unchallenged for years while all these people treated with UESWL suffer both in health and wealth as pawns in this massive and dangerous swindle. It is outrageous and grotesque.

Were UESWL merely a pill, there would be widespread public media frenzy about the safety issues, and all fingers would be pointing to the evil "pharma" giants. But because it is the urologists themselves with their so-called "non-provider ownership business interests" in UESWL perpetrating the crime, the scandal is permitted to remain behind the curtain? I don't buy it. It cannot be justified, because it is an absolute amoral human catastrophe in which the cost to so many is just monumental both in life and treasure. That this is permitted to continue as before violates human rights, plain and simple.

I am absolutely certain that many urologists will be relieved that none of them had to be the one to have had to come forward out of good conscience and tell the truth about UESWL – though they know the problems, they are afraid. I have been told this specifically by respected academic urologists. I have worked closely with urologists since 1986, know their "culture" very well, have seen it evolve over a generation, and I know that there is a silent pact; nary a one of them would ever throw another under the bus. But the UESWL scheme has become far, far "too big for their britches." Someone had to have the ethical principles to stand up and expose this catastrophe in lieu of these 8,000 silent conspiratorial urologist cowards. I came forward to save lives and expose a massive secret multibillion dollar money scheme that incentivizes gravely harmful medical practice. How was I so wrong here? What really happened with my complaint?

My fear from experience with the world of medical and legal professionals is this: that like the doctors no attorney as well, even in an agency such as yours, would ever throw another attorney under the bus and challenge their competence or ethics. Throughout the past year and a half of me trying to find an attorney to give me answers, no one is ever willing to say anything whatsoever about the quality of another attorney's work. I have had to find on my own some sort of avenue for getting to the bottom of this, and so I am coming to you. If you are not willing to properly investigate my claims here, then I need to know who next has the authority to do so, please.

You can imagine why I have a very difficult time trusting this process. Nonetheless, I will do whatever must be done to make sure I have received complete and proper representation from my attorneys and that they upheld their professional responsibilities to execute my case with all my claims as the law dictates. Because based on how they executed my case compared to what I claimed, there are deep and troubling discrepancies. What they represented to me simply does not add up based on what I am finding out about other similar cases, and although I have not been able to access legal assistance, I want to ensure that an appropriate authority can provide me clear evidence that I have been justly and competently represented and treated within our legal system. When we say "with liberty and *justice* for all," this needs to be meaningful and not just an empty crock.

I am happy and willing to discuss this all at length, under oath, and on record. It is completely incomprehensible that my complaints could ever have been thrown out of the system unless there were grave and distinct errors in judgment or competence by the attorneys involved. And if the case was just too big, perhaps, that it would just cost too much within the USDOJ budget, then I want to know that, too, because it is at that point I shall do everything in my power to be the very public voice of such a dangerous failure in our government and our system of justice. If the USDOJ and DHHS and OIG cherry-pick easy "pharma" complaints in lieu of serious major catastrophic human disasters like those caused by UESWL, the citizens of this country need to know.

Thank you very much for your concern and for investigating my complaint. You may reach me at any time by phone at (708) 763-0501 or (312) 771-2061, or email at *ae_mitchell@comcast.net*. Again, thank you.

Sincerely,

Anne Mitchell

Cc: OIG
Senator Debbie Stabenow
FDA
Public Citizen

Anne Mitchell
PO Box 3249
Oak Park, IL 60303
March 15, 2014

Michigan Attorney Grievance Commission
243 West Congress, Suite 256
Detroit, MI 48226-3259

RE: Summary Supplement to Letter

To whom it concerns at AGCMI:

The following represents a summary of facts in addition to my other letter to you concerning my request for investigation into my case: Case # U.S. E.D. Michigan (10-C-6793) (2:11-cv-10090). This case was originally filed in U.S. N.D. Illinois, and transferred to E.D. Michigan. I believe my attorneys (documents included) may have seriously messed up and prejudiced my claims by how they constructed and executed my complaint. Certainly I am fully able to provide substantially more detail. I have also included a separate letter which provides more detail, copies of some written documentation, and a "jump drive" with far more documentation. I apologize I am unable to afford the cost of copying all this material – I have been unemployed in my profession now for nearly five years. Thank you in advance.

1. I left my job with United Medical Systems (UMS) in October 2007 under the premise of "constructive discharge."
2. Following two years of very harmful and continued retaliation against me by UMS, and my personal struggle with what I had learned about how the "business" of UESWL in the United States was corrupting the medicine and patient safety with UESWL, I endeavored to "blow the whistle."
3. I began investigating how to find the best attorney(s), and contacted the organization "Taxpayers Against Fraud" (TAF). In spring of 2010, I spoke at length to Mr. Patrick Burns at TAF, whom thereafter recommended I contact either of three attorneys. I placed phone calls to these three firms in which these attorneys worked and the first to call me back was Ms. Monica Navarro of *Frank, Haron, Weiner, and Navarro* (Troy, Michigan). Ms. Navarro seemed to me to have very good understanding of the critical aspects of my complaint, so we agreed that I would travel to their Michigan office, bring all my documentation, and go through the details of my complaint in a meeting.
4. I met in Michigan with Ms. Navarro, Mr. Louis Szura, and Ms. Sue Nolan in May/June 2010 at their office, and soon thereafter we entered into a contract for them to represent me as a relator in a "class action" qui tam complaint.
5. Because my complaint also included a substantial claim for violation of the Equal Pay Act (retaliation by UMS against me included many forms but they had also paid me less than 40% of what they paid men in the same jobs with the same responsibilities and with

the same job titles), Ms. Navarro recommended I contact a Chicago attorney, Ms. Robin Potter, to represent the portion of my complaint for Equal Pay Act violations. (In July 2008 I had already filed a complaint for Equal Pay with the EEOC which was in a mountainous pile in the Chicago EEOC office waiting to be investigated). I had asserted that my claim for constructive discharge was that (a) I could not work for a company that I knew was both highly unethical and breaking the law and, (b) that was not paying me equally as a woman for my work.

6. After I entered into contract with Robin Potter & Associates for the Equal Pay violation, the attorneys from both firms agreed they would act together on my behalf in a separate agreement between themselves.
7. Together the two firms decided after that because the qui tam complaint was going to be filed "under seal," that they would compromise my "constructive discharge" claim and pursue only those aspects of it that pertained to the Equal Pay complaint. I was made to trust this was a good decision by these attorneys, however, it defeated the most salient and damaging aspect of my complaint – that this company, UMS, as a member of a class of companies with "urologist-owners" as the source for patient referrals together were in fact concealing grave and deadly harm from the procedure they "sold" in favor of what amounts to hundreds of millions of dollars or more from carefully crafted cooperative "kickback" arrangements. I left the company because UMS did not pay me equally and because I discovered they were requiring me to break laws (False Claims and otherwise).
8. Later, this decision by the attorneys to forsake the whole truth of my "constructive discharge" in crafting this compromise within the two separate complaints served as it turns out to compromise my ability to gain a just result from their decisions how to handle my complaints. The constructive discharge complaint within the Equal Pay complaint was thrown out by the judge. But this judge (Hon. Amy St. Eve, N.D. Illinois) had no knowledge that I was unwilling to work at a company where I was being forced to break the law – surely this is cause enough to leave an employer under "constructive discharge." My attorneys kept this information from the judge while the *qui tam* case remained "under seal."
9. The *qui tam* case was filed "under seal" in October 2010.
10. Though it was the principal reason I came forward, that deadly and very harmful dangers of the procedure UESWL were being carefully concealed and callously ignored on purpose by the "urologist –owned businesses," that people were being killed and badly harmed in significant numbers without oversight, that serious problems were neither being reported to the FDA nor were they being truthfully represented to patients in informed consent, my attorneys, specifically Mr. Szura, told me repeatedly that I did not have "standing" to come forward with this aspect of my complaint.
11. Throughout our contracted relationship I continued to question why I did not have "standing" to complain about the substantial and broad-scale harms that were being intentionally concealed by these "urologist-owned" companies from the FDA and from patients. I explained to my attorneys that there was no way that patients could connect

the dots of the harm they suffered to the actual UESWL procedure, and that was the reason I wished to file this complaint at all.

12. Mr. Szura repeatedly asserted that I did not have "standing." He explained that my only standing would be if I were a patient who had undergone the procedure myself and had been harmed by the procedure. I found this whole line of reasoning by my attorneys to be extremely puzzling and it did not make sense at all to me. I continued to question Mr. Szura.
13. These attorneys filed my complaint to reflect only *aspects* of my true complaint, not the whole. They decided that I had "standing" to explain the details of how financial incentives amounted in fact to "kickbacks" for the referral of patients in violation of the "in cash, or in kind" Stark II and Anti-Kickback statutes. And these "kickbacks" amounted to "False Claims" against the government (see complaint).
14. My attorneys assured me that explaining the patient harm issues (for which they asserted I had no "standing" to reveal) to the US Attorneys would substantially enhance the US DOJ and OIG's "interest" in my complaint. I remained very concerned about the complaint as they filed it, because on face value it appeared that without formally raising the very serious safety issues of UESWL in the complaint itself, the Defendants would be able to pour unlimited resources (gained from the financial scheme they were benefitting from) into defending their carefully carved-out "Fair Market Value" exception in the Anti-Kickback and Stark II statutes. These "businesses" as a class had organized a lobby (American Lithotripsy Society) spending millions of dollars to create this "exception," and create a smoke-screen in the self-referral (Anti-Kickback/Stark II) laws pertaining to "Fair Market Value," that specifically benefitted their UESWL "businesses." They had already created this law for themselves, so I believed that if the DOJ/OIG could not view my full complaint comprehensively and see that the law itself was being used to conceal very grave and dangerous patient safety problems I feared my complaint would not be taken seriously.
15. That is what appears to have happened. On February 16, 2011, I met together with my attorneys and attorneys and agents from the Department of Justice and the HHS OIG in Detroit, Michigan. They asked me questions, and I answered the questions they asked. Several of the key attorneys were in quite a hurry to get to the airport to catch planes back to Washington, DC. I never was able to assert my true complaint about the serious patient safety issues that were being hidden in favor of the success of these urologist-owners and managers businesses created solely for cashing in on the powerful and massive financial scheme. There was no time left at that meeting as they hurried to leave, and I was not asked any further questions ever by them after that single meeting.
16. I have no way of knowing what my attorneys had been conveying or discussing about my complaint or my assertions to the attorneys at the DOJ or OIG. Mr. Szura explained to me that his "point" of contact at the DOJ was the AUSA Mr. David Finkelstein, from the Washington, DC office, though the complaint had been transferred to the E.D. Michigan District of the US DOJ. Later, I became aware that Mr. Finkelstein at that time was barely out of his clerkship after just graduating law school.

17. Following the February 16, 2011 Detroit meeting, I have reason to believe the US DOJ began their investigation into my complaint. Though it was being investigated, and Mr. Finkelstein in the Washington DC US DOJ office was as I was told by Mr. Szura to have been the point of contact for my case, I learned after the US DOJ had failed to move forward to prosecute my case that the once-heralded head of the US DOJ Healthcare Fraud Division there in the Washington DC office, Thomas Zeno, left his position at the end of May 2011 and went to work for a firm, *Squires Sanders*, to represent key Defendants in my complaint. This alone, upon learning it, was extremely alarming to me. Later, I was told by Mr. Szura, that "yeah, this happens." I find it deeply disturbing, and have no recourse to know anything about the depth of what appears to be a deadly conflict of interest even within the US DOJ affecting especially those people who have been harmed by the scheme I was complaining about.
18. Beginning in late 2011, Mr. Szura began to send signals to me that he was getting feelings of concern about the US DOJ not proceeding with my case, but I believe that he did not have any knowledge then whatsoever of what Mr. Zeno had done, leaving the US DOJ and going to work for the politically powerful AKSM Defendants in my case. It all had become very frightening and extremely unsettling for me by that point, as it was already stressful enough to have endured what I had already endured. I couldn't believe I had never once been given the opportunity to explain the cover-up of the safety problems, and that they were never going to offer me this opportunity.
19. Of course as the next few months passed, Mr. Szura began to gently ask me to prepare for the case to be dismissed and unsealed. I was mortified because the whole thing seemed to me to have gone so tragically wrong. It did not make sense to me. I believed that I had taken all the appropriate steps to expose what I knew within our established legal framework so that people's lives would be saved and a gigantic financial conflict of interest would be exposed as the incentive for doctors to conceal the grave and deadly harm they had full awareness of.
20. By summer of 2012, I was repeatedly, relentlessly implored to "voluntarily" sign a dismissal of my claim. I was given no understandable explanation by my attorneys about what had gone wrong. *Something*, clearly had gone very wrong. Later I began learning more by what Mr. Thomas Zeno and Squires Sanders published on the internet about my complaint. But I never learned the full story. And I was never given the critical opportunity to expose my full and true complaint.
21. In July 2012, I was told by my attorneys that they could no longer represent me in my complaint. I was told that without the US DOJ taking part in my complaint that it was almost entirely certain I would not find attorneys to represent me and my complaint. I was told by Mr. Szura that I had ninety days to move forward with my complaint once it was dismissed or find attorneys that would move forward on my behalf. I was told, "We win some; we lose some. Just reinvent yourself and get on with your life and get yourself some mental health help."
22. In August 2012 under extreme duress I "voluntarily" signed what they forced me to sign.

23. Then I attempted unsuccessfully for the next ninety days to find legal assistance. I continued throughout 2013 to seek legal assistance in this matter, without success.
24. In February 2013, I decided that without any legal assistance I would come forward the best way I knew how with the serious claim I had always asserted about the serious patient safety issues and how they related directly to the improper financial schemes in the "non-provider -urologist-owned businesses." I went public first through the Michigan Department of Community Health Certificate of Need Commission supplying public comment about the nature of UESWL as a dangerous and unsafe procedure. I continued with additional public comment on the same subject to them in June 2013, August 2013, and September 2013 (documents included).
25. In July 2013 I filed a formal complaint with the FDA about the serious cover-up concerning safety issues with UESWL. By all accounts, from the response letter (document included) I received and an additional phone call from Ms. Kim McIntosh and emails from Ms. Donna Engleman and others at FDA, the FDA is taking my complaint about UESWL being unsafe very seriously.
26. I am aware that there have been other past federal interventions (FTC and OIG) with a "non-provider-urologist owned" UESWL "business" based in Chicago (included) related to price-fixing, and Medicare fraud. ***But***, I came forward because I had learned that it was ***NOT ONLY*** shady and sketchy financial arrangements about "False Claims" involved with UESWL, but a very serious and very harmful cover-up of massive proportion about UESWL not being safe and being deceptively and fraudulently represented to patients as being "safe" when it was not. These urologists and their partners endeavored, carefully planned in fact to very consciously neglect taking appropriate measures to address their distinct medical professional responsibilities concerning very serious safety concerns.
27. **NO ONE ELSE** has ever come forward with this information, and this is why I came forward. I felt entirely responsible for what I learned to expose it in order to save lives and prevent harm. What I learned about the very nature of how these doctors and their business partners hide these serious matters was the reason at all that I decided to "blow the whistle." They are "falsely claiming" safety above all. They, within a very large and organized collective, have manipulated the scheme into existence in order to line their pockets. They constructed a highly sophisticated smoke-screen to cover it up.
28. I have been told that since I formalized my public comment to the Michigan CON Commission, the numbers of these UESWL procedures being performed there have diminished considerably. However, I believe it is going to take time for these "urologist-owners" to figure out whether it is in their best personal interests to just keep doing what they are already doing, effectively doubling-down and not changing anything about how they are utilizing UESWL just to protect themselves, or to finally take this public exposure of their scheme seriously and face the disaster they have created.
29. I continue to provide information to the FDA, but am not permitted access to their findings from their investigation at this time. The urologists have been permitted by a broken system to deceive others and create the ultimate consent decree for themselves by

virtue of their power and position. They know what they are doing. They would like to believe that they can place all the blame on the FDA, and I suspect this is how they will play this. But the doctors are completely responsible for this – they should have gone directly to the FDA with their concerns.

30. This is a major catastrophe, and I believe based on other cases where insider "whistleblowers" have exposed serious patient safety issues (included), that my attorneys may have seriously prejudiced my claims by improperly representing my claims and my "standing" for my claims in the complaint as they drafted it and formally represented it.
31. Had my attorneys clearly compelled within my formal complaint that the crazy UESWL financial schemes were covering up the patient safety problems, I believe a very different outcome would have become reflective of what I had been attempting to expose all along.
32. Therefore, I wish to gain a very clear explanation with all the substantiating legal precedent behind it that clearly demonstrates how I did "not have legal standing" to bring my claims. If others in similar cases had "standing," why is it that I did not? If I did in fact have standing, then I wish to pursue this. I am not an attorney, I have not had the luxury of the ability to find an attorney nor pay for their services out of pocket. I have been made to struggle mightily to sort my way through this system in the name of justice, even to just find my way to your organization. There can be no trust in this system if one cannot find the competent legal assistance one needs to seek justice. I believe what has happened here has been and continues to be very, very serious and a deeply and deadly tragic miscarriage of justice.

Sincerely,

Anne Mitchell
Phone: (708) 763-0501

Cc: OIG
Senator Debbie Stabenow
FDA
Public Citizen

Anne Mitchell
P.O. Box 3249
Oak Park, IL 60303
March 24, 2014

Michigan Attorney Grievance Commission
ATTN: Complaint Intake
243 West Congress, Suite 256
Detroit, MI 48226-3259

RE: Case # U.S. E.D. Michigan (10-C-6793) (2:11-cv-10090)

Dear AGCMI:

On May 15, 2014 I sent your office the material for review of my formal complaint against my attorneys (Szura, Navarro, Nolan). I'd like to supplement this material with copies of documents that are germane to my complaint which I'd neglected to send the first time, please.

It is extremely important to note what has transpired very recently and in 2010 with several of the Defendants in my *qui tam* complaint in response to both the legal actions in 2010 taken by the U.S. Department of Justice and in response to the letters I submitted to the Michigan Department of Community Health Certificate of Need Section in 2013. These actions by these Defendants serve to punctuate their fear by the urologists for me having blown the whistle and spoken out about their deadly cover-up of the safety problems with UESWL.

1. *"Healthtronics"* and "*United Shockwave Therapies*," both operating under hundreds of other aliases, have been over the past 25+ years the most vocal and militant of the physician-owned UESWL businesses. They have been the most active in lobbying legislators to keep their little enterprises from becoming a "Designated Health Service" under the Stark II laws, and have secured the carve-out provision in the Anti-Kickback law for "fair-market-value (FMV)" to keep their businesses running on all cylinders. Their most militant claim for gaining ground in their businesses were that they were owned and run by urologists – this armed them in convincing ways to tout the highly superior "quality" of the services they sold. Right.
2. During the time "*United Shockwave Therapies*" was under investigation in 2010 that ended with them paying a fine and entering into a Corporate Integrity Agreement with the U.S. Department of Justice (http://oig.hhs.gov/fraud/cia/agreements/united_shockwave_07082010.pdf), everyone in the industry knew what had been going on – that "UST" was being investigated. Why? Because everyone in this massive national UESWL collusion talks to everyone. Why? Because they are so afraid of the truth. So, fear of course set in, and it clearly felt like the USDOJ was just getting a little too close for comfort. So, "*Healtronics*" put themselves up for sale. All these UESWL operators are doing essentially the same thing, so you can imagine their level of fear. Dr. Argil Wheelock, Founder of *Healthtronics* obviously wanted to get as much cash as he could and remove himself at least somewhat from the "situation."
3. *Healthtronics* was sold to Endo Pharmaceuticals (very strange bed fellows, indeed) and an announcement was made just within days of the announcement of the USDOJ CID

with *United Shockwave* on July 8, 2010. Just in the nick of time. Surely Dr. Wheelock made a bundle.

4. When the seal was lifted in my *qui tam* case in August 2012 the UESWL players were all getting very itchy. I personally think that it was because my case was dismissed *without* prejudice by Judge Roberts.
5. All these extremely loud and proud "urologist-UESWL-owners" started losing some of their hot air. Why, because they knew who I was and knew what I know.
6. Then, beginning in February 2013 I began making my written comments public at the Michigan CON Department. These letters to Mr. Falahee and the Michigan CON Commissioners just kind of went viral around the country.
7. My ex-employer, *United Medical Systems (UMS)* tried to sell their company to "*Universal Hospital Services*" out of Minneapolis. But when I heard this, I contacted *Universal Hospital Services* and emailed them copies of my letters to the Michigan CON Commission. (see documentation of August 7, 2013) This sale of *UMS* then never happened.
8. Suddenly, on November 20, 2013 (see documents) United Shockwave (with all their hundreds of LLC aliases) was sold to "Bison Capital!" Just how would they now be able to claim they were owned by "urologists?" Well…According to Bison, this was to ensure that their masterminds, Donald Norris, MD, and Marc Rubenstein, MD would get their extremely nice payout before the shit would inevitably hit the fan with the FDA. Nice guys. Wise-guys.
9. Then, on January 9, 2014 it was announced that Endo Pharmaceuticals divested themselves of "Healthtronics" for $85million to "Altaris Capital Partners;" this after Endo had only just purchased Healthtronics on July 20, 2010 for $233million! Do you think Endo just didn't want to get their hands dirty again with the FDA? What's a couple hundred million, anyway?
10. So, suddenly all these highly-touted "urologist-owned" masterminds of the UESWL industry are slinking away and selling themselves to the hedge fund managers. Why? They are using their "business" might to get as much cash as they can quickly before the truth comes out about what they have been doing for the past thirty years. They want to appear now to have distance. As in, "What? Who, me?" But they know what is inevitably going to happen. UESWL is unsafe and they know it. Just where the hell do all the patients come in here – they're the ones who're paying for all this!!!!
11. It is also important to predict how all this will play out for these Hedge Fund/Venture Capital guys – the urologists who supply the patients to their newly purchased little UESWL partnerships have no reason whatsoever to have allegiance to someone with the name of "Bison Capital", or "Altaris Capital Partners!" I mean really, c'mon! These urologists can just as easily pick right up and formulate their own new LLC partnerships in a heartbeat and leave these capital guys in the dust. Why? Because no one can tell a doctor what to do with their patients. If the urologists can find a sweeter pay-out somewhere else, they'll pick right up and move on.
12. But, now that the writing is on the wall about their little UESWL safety secret, it seems everyone but these sucker capital guys knew. And these urologists like Wheelock, Rubenstein, and Norris are just laughing all the way to the bank.
13. It is highly likely that Allied Metro Litho, AKSM, and UMS and all the others are all out their trying to do what they can to divest as well – so I suggest you watch what they're doing now. Here's the thing, though – I know that at least UMS and AKSM know that the FDA is investigating: I sent an email to Thomas Zeno, AKSM's attorney at Squires

Sanders so he knew. If Zeno told his clients AKSM, then Dr. Wise surely told everyone else along the national UESWL hotline.

14. Also, important to note – the "*Council for Urological Interests*," the outrageously loud lobby run by the UESWL Outfit, who used Thomas Mills of Winston Strawn as their lobbyist, has just suddenly disappeared from the internet! Their very brazen website, filled with all their bluster about how they were ensuring the rights of urologists to provide lithotripsy under ownership just disappeared, and now what shows up in its place is some sort of scam for Viagra sales! Check it out: http://urologicalinterests.com

This is all very germane to my complaint because timing is everything. These UESWL operators are mighty scared now and always have their fingers on the pulse. They know that UESWL is unsafe, and they are reacting now that the cat is out of the bag. Had my qui tam complaint been properly constructed I would never have needed to go public with the FACTS about these very grave safety issues with UESWL later. Had my attorneys properly executed my qui tam complaint, these safety issues would have been raised directly in the complaint, because it is the safety issues that the urologists are afraid of. They should be very afraid for what they've done to people. Urologist-owned UESWL "business" took precedent over the proper safety of their patients' lives – each and every one of them knows this. And now that the cat *IS* out of the bag, these crooks are running for their own lives, grabbing as much money as they can and running for the hills.

Meanwhile, amidst all these outrageous money games, the patients continue to be harmed in unspeakable ways with UESWL. This is a crime of unfathomable, unspeakable proportion.

Thank you.

Sincerely,

Anne Mitchell

Cc: OIG
Senator Debbie Stabenow
FDA
Public Citizen

Westlaw Journal
HEALTH CARE FRAUD

Litigation News and Analysis • Legislation • Regulation • Expert Commentary VOLUME 18, ISSUE 4 / OCTOBER 2012

Expert Analysis

Yes, Virginia, The Government Listens

By Thomas Zeno, Esq.
Squire Sanders (US) LLP

The government repeatedly urges companies to implement compliance programs that can be expensive and time-consuming. Even as it continues to demand major fraud settlements, totaling more than $4 billion in fiscal year 2011, from some companies, the government has indicated that it will treat companies differently when they are structured to operate in compliance with the law. This is a story about a company that took the government at its word. Although the journey was not easy, the story has a happy ending.

The subject of the story is Greater Michigan Lithotripsy, a joint venture that is owned by urologists and provides lithotripsy services for its patients. Lithotripsy is a noninvasive surgical procedure for treating and removing kidney stones by smashing the stones with sound waves so that they can be passed out of the body.

The day-to-day operations of GML are overseen by American Kidney Stone Management Ltd., a nationally recognized leader in providing lithotripsy services. AKSM provides state-of-the-art mobile equipment that can be transported in vans so that patients can be treated in facilities close to their homes. AKSM employs a national medical director as well as regional medical directors to ensure that quality service is delivered on AKSM-owned lithotripsy equipment.

to January 2004. The CID gave no indication as to how the investigation began, what allegations had been made or who had made the allegations.

Pursuant to 31 U.S.C. § 3733, a Justice Department civil attorney may issue a CID in furtherance of a false-claims investigation. As the civil equivalent of a grand jury subpoena, a CID can be issued only prior to filing a civil complaint. By issuing a CID a civil attorney can require production of documents, responses to interrogatories and provision of oral testimony. The civil attorney is not required to provide reciprocal discovery and does not need to provide a detailed explanation to the recipient about the investigation or what other evidence has been assembled.

Although it has been available to civil attorneys for years, historically the CID rarely was used because it required the personal approval of the attorney general, which involved more bureaucratic delay than most attorneys thought was worth their while. As part of the federal government's crackdown on fraud, not only in health care but in all its forms, Congress passed legislation authorizing the Justice Department to modify the CID process. Since 2010, the U.S. attorney in each district in the country as well as the assistant attorney general of the Civil Division has the authority to approve a CID. The increased use of CIDs was immediate and has been substantial.

By issuing a civil investigative demand, a civil attorney can require production of documents, responses to interrogatories and provision of oral testimony.

Describing the depth of anxiety caused by receipt of a CID is difficult. The urologists who owned GML are outstanding physicians trained and dedicated to healing their patients. When establishing the company, they went to great lengths to structure and operate it in compliance with the complex laws imposed upon the health care industry. The idea that GML had been violating the law at all, let alone for seven years, struck the doctors like a thunderbolt. What were the charges against them? What did the government want? What should they do in response? Making these questions more urgent was the fact that the investigation prompting a CID often can be initiated by the allegations of a whistle-blower contained in a *qui tam* complaint that has been filed under seal pursuant to the False Claims Act.

Seeking treble damages and penalties, a *qui tam* complaint could have destructive consequences. GML was anxious about this possible result because, in 2010, the Office of Inspector General had settled its investigation of another lithotripsy provider by requiring that company to pay $7.3 million and enter into a five-year corporate integrity agreement.

THE CHOICE OF APPROACH

Obviously, protecting a client from the unseen forces behind a CID is the prime objective when responding to it. There are so many good reasons to play it by the book, be careful and go slowly until things become clearer. In this case, GML wanted to be more proactive by explaining its operations and its history of compliance.

Based on my experience of nearly 30 years as an assistant U.S. attorney in Washington, I knew too well this could be a risky approach. Some would even say that believing in the government is like believing in Santa Claus. After consultation and not a little soul-searching inside the company, however, the decision was made to see whether the government would listen.

THE GOVERNMENT'S OBJECTIVE

The decision to cooperate took into account the government's overall attitude toward *qui tam* litigation. The government encourages these suits because it realizes as much as a $7 return on investment for each $1 it spends on false-claims investigations. The practical side of this equation explains why the government would be willing to listen

to a request to end an investigation. Civil attorneys are being inundated with false-claims actions in a time of budget cutbacks in government.

Because only some *qui tam* relators provide information worthy of investing government resources in a protracted investigation, civil attorneys intervene in *qui tam* cases about 25 percent of the time. That means they decline to intervene about 75 percent of the time. Civil attorneys are motivated to listen because they want to know quickly whether a matter should be pursued. If the case has merit, they will pursue it doggedly. If not, they have plenty of other places to look for work.

THE E-DISCOVERY GIFT

Regardless of how ready to listen they might be in the long run, the civil attorneys needed a demonstration of GML's good faith in the short term. The first step toward convincing the civil attorneys to look elsewhere was GML's production of documents responding to the CID. Given the size of the demand in the CID, GML was facing a burdensome fee just to have the documents collected and reviewed for relevance and privilege.

Fortunately, civil attorneys commonly recognize the breadth of a CID, and they normally are willing to discuss how to focus production on the documents that will affect their decision to intervene. After courteous and substantive discussions between us and the civil attorneys, the universe of documents to be searched in the initial production was reduced from a starting number in the millions to about 650,000. This agreement still left GML facing a substantial fee for document review.

In order to provide the most cost-efficient and accurate document search available, we suggested to the government that we use the Squire Sanders predictive coding software called Equivio. In contrast to expensive human document review, which, even with keyword techniques, can retrieve as few as 25 percent of the responsive documents, predictive coding is highly accurate. Equivio takes the guesswork out of the e-discovery process by organizing the document collection by responsiveness, enabling litigators to focus their efforts on the most important documents. The process is far less expensive than traditional document review because it involves just a few litigators well versed in the document search who rank responsive documents.

The civil attorney is not required to provide reciprocal discovery and does not need to provide a detailed explanation to the recipient about the investigation or what other evidence has been assembled.

Revealing the practical side that we hoped to find, the civil attorneys were intrigued to try an approach that would be faster, less expensive and more accurate. After numerous discussions, the civil attorneys were willing to try it. At the end of the ranking process, the number of responsive documents had been reduced from 650,000 to 11,000, with a projected accuracy rate of 90 percent. When the civil attorneys began reviewing the results, they were completely in agreement about using Equivio because they were reviewing only highly relevant documents. Although it was a win-win solution, GML still had to bear a significant fee. Fortunately, it was substantially smaller than it appeared at first.

UNWRAPPING A SURPRISE PACKAGE

Civil attorneys use partial unsealing as another way to focus on *qui tam* cases most likely to produce a recovery. After obtaining permission from the court, civil attorneys provide a copy of the complaint to defense counsel and request a substantive reply to the allegations. The copy remains under seal and may even be redacted in part. The advantage of this process to the government is that the complaint has not yet been served so the government can get a substantive response to the allegations before deciding whether to intervene. The advantage to the defendant is the opportunity to influence the government's decision to intervene.

The civil attorneys provided a partially redacted complaint in spring 2012 and requested our response. Although this was the kind of opportunity we had been seeking, the scope of the allegations in the complaint was daunting. Instead of making allegations against just GML, the complaint amounted to an attack on the lithotripsy industry as a whole, listing pages of urologists and organizations that allegedly were defrauding the government while providing lithotripsy services.

For good measure the complaint ended by including "John Does 1–10,000." On the list of those specifically named was AKSM itself. This broad-based attack on lithotripsy services implicated not only GML but any of the joint ventures that AKSM managed on a daily basis, as well as practically every similar type of venture in the United States.

TELLING OUR SIDE

Despite the disquieting scope of the complaint, our team seized the opportunity to make a substantive presentation to the government to refute the allegations. We assembled a detailed explanation of the model used by AKSM and GML to provide lithotripsy services. A substantial portion of the presentation focused on the manner in which AKSM structures joint ventures to be compliant with OIG guidance.

We described in detail the compliance program and the code of conduct built into each joint venture. Because compliance was built into the joint ventures at the beginning and maintained through regular training, we had the documents to support our position that the allegations were incorrect as they applied to AKSM and its affiliates.

MORAL OF THE STORY

GML learned about the Justice Department investigation in October 2011. Through the responsive, proactive and cooperative approach authorized by GML and AKSM, we offered the government the opportunity to make good on its promises to respect companies that function in a compliant manner.

The civil attorneys heard our presentation in spring 2012. By August, less than one year after issuing the CID, the government had dismissed the complaint in its entirety with the consent of the relator. The anxiety and cost had been significant to our clients, but the result proved the government's promise.

Yes, Virginia, the government listens.

Via email

February 26, 2013

c/o James B. Falahee, Jr., J.D.
Chair, CON Commission
Michigan Department of Community Health
Certificate of Need Policy Section
201 Townsend Street
Lansing, Michigan 48913

Dear Chairman Falahee and Distinguished Commissioners:

Thank you and the Certificate of Need Department for your continued dedication to proffering those decisions that ensure access to affordable, quality health care for residents of this great state of Michigan. I hereby submit this letter as formal testimony on behalf of my mother, who is unable to represent herself, but would if she could. My mother is a member of the public you serve, a Michigan resident now receiving Medicare and healthcare benefits under the Michigan Public School Retiree Plan. Though I understand this public testimony is a tad late, it is intended for your sincere consideration during this time while you consider 2013 Certificate of Need Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services.

As one who understands the subject matter of UESWL and your CON review standards implicitly, I strongly support and urge continued regulation of lithotripsy services. In addition, I strongly urge you to carefully discern the most critically important facts and numbers before you prior to taking specific actions affecting performance standards of UESWL service, access to it, and the fair and reasonable cost to real people affected by your decisions. On behalf of my mother, and others who have no active, informed voice in this process, I strongly support several very distinct changes to be made in the standards for UESWL that may require a workgroup or Standards Advisory Committee (SAC) to be established.

Background

It is no secret that the main driver of our national deficits is healthcare. We are staring into the eyes of a monster borne of very near demands on our healthcare system posed by the aging baby boomers and by healthcare reform. The prices paid for healthcare services are too often wildly distorted in a system that bears no resemblance whatsoever to a "free market" system. When a patient/purchaser has no means for knowing what it will cost in advance to receive the care they need, nor the medical knowledge necessary to discern that which is appropriate, mostly during stressful times when sick and vulnerable they must instead trust that others will make these fair and just decisions in their best interest. No "free market" argument is ever remotely accurate in the describing our healthcare circumstance. Michigan CON charter is to protect the public against

unfair, unreasonable, and fraudulent practices in covered services by monitoring cost, quality, and access.

Following a mob-style coup in 2004 by Michigan urologists aided first by the large Chicago Syndicate, and then in 2005 by Spectrum Health and William Beaumont Hospital collaborating with the large Ohio Syndicate, two subsidiaries of large out-state syndicates were formed in Michigan and became the exclusive providers of lithotripsy service in the Lower Peninsula. These subsidiary syndicates are known as *Greater Michigan Lithotripsy* and *Great Lakes Lithotripsy*.

Information is widely available from all the CON Department documents from 2005–2010, reflecting numerous changes throughout the state as a result of this takeover of lithotripsy by the syndicates.

With the hostile takeover, these syndicates and their urologists conspired to gain the power necessary to substantially raise prices for mobile lithotripsy service in Michigan across the board. Their intimidating scheme permitted syndicators and urologists the ability to extract for themselves most fees paid to the facilities by insurance companies, the government, and patients for lithotripsy service. It only requires plain arithmetic to understand what happened. Since they became syndicated, it is easy to conservatively estimate that a couple hundred urologists in Michigan alone have by now extracted at least $50,000,000 in "profit" (derived of payments from patients intended for facilities) for themselves by performing lithotripsy in Michigan in addition to what they already receive in normal professional fees paid to them for performing lithotripsy. This does not even reflect the additional millions paid as well to the Outfit bosses. This profit model was derived via base intimidation.

For lithotripsy service, under CPT billing code 50590, insurance companies, the government, and patients pay Michigan CON-approved facilities money that has been calculated to be fair and reasonable for covering facilities' costs to provide: the lithotripter and technologist, operating room, recovery room, staff, lights, heat, overhead, billing services, insurance, brick and mortar, etc. It, again, merely requires simple arithmetic. When receiving an invoice for lithotripsy service from a facility, it is appropriate for a patient to believe that his payment will be used to cover costs in a transparent, fair, and reasonable manner for the services received. Patient invoices for lithotripsy services, however, do not provide the actual hidden detail when instead a facility turns over highly inflated payments to syndicates for the lithotripter and technologist. These highly inflated payments cause facilities instead to lose money unnecessarily on the transaction, in spite of what the patient is led to believe, which in turn requires a facility to either find money "elsewhere" to cover their own overhead costs for the service, or ultimately demand more money in turn from those who pay them. They rob "Peter" to pay the Outfit. The public deserves transparency in this insidious scheme, and to be respected with honest answers about why this scheme has been wrought upon them, especially in light of being a covered service under Michigan CON

guidelines for cost, quality, and access. Because of the Outfit's act so far of siphoning the $50+ million in Michigan and $$Billions nationally, people like my mother and all those other victims affected by the lithotripsy syndicates must endure cuts in healthcare coverage, loss of coverage, increases in contributions for coverage, loss of pension programs, etc., and even worse, just so that the intimidating Outfit can get paid.

Cost

In the 2007 standards review period for UESWL service, I provided testimony to the Commission that, upon performing simple math, demonstrated the cost per case to provide mobile lithotripsy service with a lithotripter and technologist is $385.00, or an annual cost of $385,000 given a standard performance of 1000 cases/single lithotripsy unit. In the 2010 standards review period for UESWL, Mr. Jorgen Madsen provided these documents once again to the Commission, and stated that the costs for providing UESWL service had not changed since 2007. I can find no reason why these costs have had any legitimate reason to increase in the last three years.

The following table represents the simple math: Current charges for lithotripsy service by the Outfit in Michigan run anywhere from $1500.00 to more than $2300.00 per procedure according to Department documents. Current global facility payments for UESWL by insurance companies and the government aren't much more than this, and if they are, they should be questioned as suspect. It is quite simple to discern profitability, and what should be considered fair and reasonable for Michigan healthcare consumers.

Charge/patient	Patients/day	Patients/year	Total/year	% Net Profit
$ 385.00	4	1000	$ 385,000	Even
$ 385.00	5	1250	$ 481,250	25%
$ 385.00	6	1500	$ 577,500	50%
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
$2400.00	4	1000	$2,400,000	523%
$2400.00	5	1250	$3,000,000	680%
$2400.00	6	1500	$3,600,000	835%

This is not complicated. It is important to note that a single unit lithotripsy service need only treat four patients each day, five days per week for fifty weeks per year in order to comply with Michigan CON performance standards of 1000 cases. A single procedure takes roughly 45 minutes. Profit increases with efficiency. It is absurd to believe as some do, that cutting those performance standards in half, basically treating only two patients per day, somehow meets CON governance standards for cost, quality, and access. It is easy to see, however, where this is coming from. I strongly urge the Commission to adopt new CON cost standards which serve the people of Michigan by capping the maximum per patient payment made to lithotripsy services at $500.00. A 95% profit by

providing efficient service is more than a fair and reasonable reward in today's desperate climate for healthcare consumers.

The game is clearly rigged where it shouldn't be, and permits the Outfit to skim their take from what everyone can easily discern to be otherwise fair and reasonable payment for covering facilities' costs for lithotripsy. For the inflated $2400 fee, does a facility receive a higher quality mobile service? No. For the inflated fee does some sort of improved quality of service guarantee a lower retreatment rate or a higher success rate? No, and probably the inverse. Does mob syndication provide the patient with a quality standard that improves outcome? No. Does the syndicated urologist have the same patient care responsibility were he not syndicated? Yes. The only difference between a fee of $385.00 and a fee of $2400.00 for mobile lithotripsy is that tens of millions of Michigan dollars in ransom is paid to the Outfit, whom in turn with their tidy take pay off public officials (see FEC Report for Committee ID #Coo489419 "AKSM Urology PAC"), and ex-public Department of Justice officials (Thomas E. Zeno, esq.) in order to protect the racket.

Once the Outfit infiltrates the process, there is no means to negotiate fair pricing based on what is known by everyone to be true about cost. Intimidation by the Outfit practically extinguishes performance and often even the legitimate consideration of lower cost alternatives for kidney stone removal, significantly increases the number of patients treated with UESWL (see Michigan CON Activity Reports) in spite of a plummeting Michigan population overall, increases UESWL retreatment rates, and most poignantly silences any statistically significant, actionable research programs that may otherwise address in proper measure the very disturbing known concerns about very real risk for life-altering, harmful adverse effects of UESWL.

Quality

In 1984, UESWL technology sailed through the FDA approval process in a short period of time. Since then, the FDA has required no critical long term follow up reporting about this technology to evaluate safety and efficacy, regardless of deeply grave concerns raised in the medical literature about harmful effects. Adverse events for lithotripsy are only required to be reported to them on a voluntary basis. Simultaneously in 1984, a handful of entrepreneurial American urologists began the process of syndicating their peers, building the Outfit that has become a massive national UESWL enterprise. This was possible by carefully fixing prices for services at highly inflated rates in order to secure a so-called "market value" favorable to the Outfit for paying off urologists, and for eliminating competitors who might come in at legitimate lower price points with better quality service. Since right around that same time, 1984, there has become an exploding epidemic 3,600% increase in the rate of acute kidney failure in the United States, the likes of which we have not seen.

As CON Commissioners you are not practicing medicine, however, as arbiters of cost, quality, and access concerns in Michigan healthcare delivery, I suggest you conduct a

thorough review of the medical literature for kidney disease, UESWL, CDC statistical reports for renal failure, dialysis, etc. This is very important information. There is an urgent need to correlate this information, because there is mind numbing radio silence by urologists, the majority whom are syndicated into the Outfit. The public would otherwise reasonably expect the urology profession to be advocating for real answers about harmful effects by undertaking critical, actionable UESWL research. In fact, not performing this research could legitimately be considered a serious breach of trust and responsibility to patient care. The reason this research is not happening could arguably be due to the massive, controlling multibillion dollar Outfit's interest for protecting their perversely conflicted financial enterprise.

With the Outfit so astutely adept over thirty years at organizing to inflate consumer prices in a closed market, syndicating the majority of urologists in this country, and showing clear and compelling capacity to administrate a crooked financial product for themselves, surely they could organize their time, power, intellect, and energies for the sake of "doing no harm." This would be nice. But it won't happen unless the public makes it happen.

There are very troubling concerns about both the short- and long-term adverse effects of UESWL treatments causing renal and other trauma, life-altering ill effects such as hypertension, diabetes, renal failure, pancreatic failure, cardiac arrhythmias, and yes, death. Death, yes, here in Michigan, caused by UESWL. But there are no studies large enough in the medical literature to warrant actions for limiting UESWL performance in response to what are highly measurable, but instead are carefully concealed, life-threatening risks.

The very distinct smoke signals about renal failure and the adverse effects of UESWL from the few brave academic urologists in the medical literature must be taken very seriously. But their studies are just never large enough to cause actions within the Outfit for altering UESWL practices. These dangerously unexamined risks are not conveyed appropriately to patients. For instance, a review of the literature showed a long-term reduction of function in the individual human kidney after SWL in some cases of a solitary kidney and in some cases with an untreated contralateral kidney. "Because there is no evidence that an untreated contralateral kidney aids the long-term recovery of the function of a treated kidney in all cases, simultaneous or separate bilateral renal SWL would not influence this long-term reduction in renal function, which was felt to occur with multiple renal stones and repeat SWL." (J Endourol 1994. Dec 8(6): 395-9.) Wow. Then, "This acute SW damage can be severe, can lead to scarring with a permanent loss of functional renal volume, and has been linked to potentially serious long-term adverse effects. A recent retrospective study linking lithotripsy to the development of diabetes mellitus has further focused attention on the possibility that SWL may lead to life-altering chronic effects. Thus, it appears that what was once considered to be an entirely safe means to eliminate renal stones can elicit potentially severe unintended consequences." (Semin Nephrol. 2008 Mar; 28(2):200-13)

Following UESWL, blood levels for BUN and Creatinine are tested. However, neither of these tests explains anything of damage that may have been done to the treated kidney, so therefore are false representations for the "safety" of UESWL. It is widely known that the untreated kidney will produce normal blood levels of BUN and Creatinine when the contralateral kidney is absent or non-functioning. This is a deeply flawed representation of "safety." The actual damage caused to the treated kidney is not adequately evaluated, and therefore neither is any longer term adverse effect of the trauma on renal function.

One said in conclusion, "SWL results in a clinically significant long-term reduction in renal function."(J Endourol. 1994 Feb; 8(1); 15-9.) Another, "the safe limits of extracorporeal shock wave lithotripsy in humans have yet to be established. Further study regarding this issue and the potential long-term adverse effects of extracorporeal shock wave lithotripsy is needed urgently."(J Urol. 1989 Mar;141(3 Pt 2):793-7). And yet another, "Both clinical and experimental reports clearly show that shock wave lithotripsy (SWL) causes acute renal effects in a majority, if not all, treated kidneys." And another, "At 19 years of follow up, SWL for renal and proximal ureteral stones was associated with the development of hypertension and diabetes mellitus. The incidence of these conditions was significantly higher than in a cohort of conservatively treated patients with nephrolithiasis." (J Urol. 2006. May; 175(5): 1742-7). But nothing actionable is being published or being done. Diabetes mellitus and hypertension cause renal failure, notwithstanding the pure traumatic events posed by UESWL.

When the study was published by the Mayo Clinic in 2006, the American Urological Association requested a response from within, and published a whitepaper:

http://www.auanet.org/content/media/whitepaper.pdf

This whitepaper was basically a wasted review of the medical literature, because the AUA already knows there is nothing actionable in the literature. It can be argued that actionable research is missing on purpose. Please note the physician (business) disclosures in this official whitepaper.

The cost of renal failure in life and in treasure is staggering in this country, and in Michigan.

It is not rocket science to consider that when there is clear evidence and awareness for a procedure causing the kind of trauma that may necessitate nephrectomy, splenectomy, or cause massive hemorrhage, renal failure, and/or death, our concern should be heightened about what this procedure is really doing to people in the long term. It is a traumatic procedure. Anecdotes are not enough. It is no big secret that money has been covering up that the brains of our national gladiators, the NFL, are permanently damaged by concussive effects. Is there really no concern for taking legitimate action to address renal function after trauma? Apparently there is not.

If a patient has had a kidney stone once, they're at significantly increased risk of having another. If this patient has been treated at first with UESWL and there has been unmeasured harm to the kidney, or other organs for that matter, then what will happen if a kidney stone forms in the patient's contralateral kidney and is then treated again with UESWL? It is important to understand the impact of what are only partially examined effects of lithotripsy trauma on the lives of real people, the other victims who pay the high price for this as well, and what the epidemic of acute renal failure is doing to our country. It is indeed arguable that high cost of UESWL syndicates may be far, far greater than meets the eye at first glance. But we will not get the answers we need to know from the Outfit. Obviously.

When others suggest that UESWL is not "invasive," whereas Ureteroscopy is "invasive," as an argument to double the access to UESWL services, be afraid. There is nothing proven in the medical literature about UESWL being more safe or more effective than Ureteroscopy. In fact, the questions raised in the literature about serious trauma and overall safety of UESWL suggest otherwise. However, badly needed research to address these real concerns has been neglected by urologists over these past 30 syndicated years, arguably on purpose. Why bite the hand that feeds?

I would suggest it is long time to come clean about UESWL. And if the urologists, those very professionals we trust in our society to act honestly and impartially on our own behalves, won't properly or adequately perform the research to fully measure the risk of harm by UESWL, then who will? Who will? Who will be the arbiter, then, of "quality?" Who will care to understand the true cost?

I urge you to conduct your own thorough medical literature and statistical review as I did. You may need to go no further than Michigan's Genessee and Lapeer Counties to see a snapshot of what has been happening.

The neglect by an entire national class of physicians (by no means is this unique to Michigan) to perform the obviously needed UESWL research is not an issue of competence. These are doctors. They were the smartest kids, and medical school was the hardest thing to do. It is an issue of character. They have no problem whatsoever organizing in massive groups of complex syndicates boasting of 2500 urologist members, 2000 urologist members, 1500 urologist members, within an Outfit that spans the entire country in order to drive up the cost of providing lithotripsy service nationwide. But there is a clear, cold, calculated neglect to organize for the purpose of conducting the badly needed research they know is necessary to tell the truth about dangerous risks of UESWL. They have known since at least 1989, and have done practically nothing. Thirty years performing UESWL. What you will find in the medical literature tells the precise story of what you will not find in the medical literature; any actionable research. No studies long-term or large enough in writing to warrant any red flags about their very real concerns. Mind you, there are many concerned urologists. But the vast majority of

them are afraid to speak up. It is practically impossible by now to find any unaffected, unbiased medical leadership on this subject amongst them. The Outfit is too powerful.

Far more than merely capping payments made to mobile lithotripsy service providers, a thorough, impartial, independent review of UESWL will provide you with clearer understanding of what might be known about both the life and treasure involved were UESWL not affected by the Outfit's control over information concerning this traumatic procedure. You simply cannot take the concept of "quality" for granted. I strongly urge you to know the subject matter.

Last year alone, Medicare spent $32,900,000,000 on acute renal failure in the United States. This is an unimaginable annual figure considering these are patients who first suffer in dire misery before facing certain death from their disease. One out of five of these patients die every year from their renal failure. The cost is just staggering. With proper attention, and money spent appropriately, these conditions can more often than not be prevented. Protecting UESWL from well-warranted scrutiny must stop. If the urologists and the Outfit won't be forthright with the answers we need, the public deserves real answers for these failures from our governing authorities. The cost is simply far too high. It is not nothing. There must be impartial, informed oversight for those who are picking winners and losers in life and death circumstances for a very pretty penny.

Were there to be an organized Outfit for every medical procedure, then what? This is not complicated. "Quality" must mean something, and the paying public has a right to be respected and kept clearly informed. It is time for the needle to start moving in the right direction concerning hyper-inflated healthcare costs for no good reason and quality care that can be measured honestly. UESWL must be met with the critical unbiased scrutiny it deserves.

With one hand picking the pockets of Michigan healthcare consumers, the "AKSM Urology PAC" aided by Michigan urologists has used the other hand to feed this money to the likes of Ohio's John Boehner and his "The Freedom Project." My mother, and I would guess many other Michigan residents whose wallets have been emptied, would like an answer to these questions: Who's "Freedom?" And, who's "Freedom" to do what?

Access

Access to UESWL is obviously not a problem in Michigan. One need only examine the CON Activity Reports. Eliminating the costly, inaccessible fixed-based lithotripters solved that problem. Now the question of too much access must be answered. It is time for the paying public to understand in a transparent way who is treated with UESWL, and why they are treated with UESWL instead of lower cost alternatives. The paying public should know answers the urology community refuses to give them about who is harmed by this procedure. I would suggest that a tracking mechanism be adopted for UESWL

similar to that of MRI standards for "Available Adjusted Procedures," which may include a statewide registry. This is a critical problem that must be met with a transparent solution. With increased access, increased responsibility for the facts must be exacted.

Summary

We support and urge capping the charge by lithotripsy service providers to facilities at $500.00/procedure. We support and urge an informed, impartial SAC be formed to address a process for knowing the true cost that UESWL has wrought upon Michigan.

Michigan alone is by far not the "problem" related to what is happening with UESWL syndication in the United States. But, Michigan can be the solution. The choice before you is to reject intimidation by the Outfit in favor of reducing healthcare costs for real people and improving the quality of knowledge we have about a traumatic procedure and its relationship to a deeply catastrophic epidemic of deadly kidney disease. We urge you to find other means to support urologists in legitimate ways to do their good work. We urge you to do the right thing.

Thank you for your service.

Sincerely,

Anne Mitchell
ae_mitchell@comcast.net

Cc: The Public

June 13, 2013

c/o James B. Falahee, Jr., J.D.
Chair, CON Commission
Michigan Department of Community Health
Certificate of Need Policy Section
201 Townsend Street
Lansing, Michigan 48913

Chairman Falahee and Distinguished Commissioners:

Thank you and the Certificate of Need Department for continued dedication to proffer decisions that ensure access to affordable, quality health care for residents of Michigan. I hereby submit this letter as formal testimony on behalf of my mother, a Michigan resident who is unable to represent herself but would if she could. My testimony is intended for your sincere consideration during this time while you and your workgroup consider 2013 Certificate of Need Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services.

UESWL is an *EFFECTIVE* means for treating kidney stones. UESWL, however, is not a *SAFE* means for treating kidney stones. Shockingly, no pun intended, safety has not been proven. The term *SAFE* cannot simply be used interchangeably with the term *EFFECTIVE*. In 1984, under extremely heavy pressure by American urologists to approve UESWL technology in the United States, the FDA abdicated. It could easily be seen that UESWL worked; kidney stones could be "pulverized" as they claimed. But it was also demonstrated that ESWL could just as easily destroy lungs, spleens, the pancreas, kidneys, normal heart rhythms, etc. To this day, nearly thirty years later, without good faith research the FDA had entrusted to the urology community, the *SAFETY* of UESWL remains no more than a matter of wishful thinking.

The *FACTS* heretofore concerning UESWL safety have proven highly inconvenient for economic interests of American urologists; simultaneously in 1984, a plan was hatched and UESWL became a booming "service business" for urologists to make a lot of extra money. A lot of extra money. Urologists assumed the conflicting duality of roles as both physicians to patients and producers to shareholders. Creating this vehicle for so much extra money is based entirely on inflating contract prices with healthcare facilities and increasing patient volumes treated with UESWL services in which non-provider urologists have so-called "ownership" shareholder interest. The more patients treated with UESWL, the more money these syndicated urologists ("shareholders") make. It must be a volume-based business; just ask the "*Council for Urological Interests.*" Wink, wink, nudge, nudge. A UESWL "service" syndicate typically consists of merely providing a lithotripter, technologist, truck, and driver under contract to healthcare facilities.

Research shows that after thirty years we still don't know which patients should be treated with UESWL and who shouldn't. It is entirely possible that hundreds of thousands of patients who've been treated with UESWL may have been far more safely served by alternative treatments. But a lot of extra money stands directly in the path for any adequate medical research to measure grave safety hazards of this technology and establishing any properly vetted patient selection process. It is highly offensive and mocks patients' distinct rights to in any way sanitize the brand of sheer plunder that is urologist-syndicated lithotripsy "service." The neglect for proper research to be conducted when safety has not been proven over three decades has had dual effects: (1) It creates an operating environment in which safety somehow became a dangerously false assumption, and (2) it robs patients the freedom with which to make highly consequential medical choices based on factual science, I might add whilst they are often in agonizing pain.

Today we are publically witnessing that standard mainstream economic theory construes all our motivations, whatever their character or source, to be "preferences" and assumes they are additive. However, this blindly misses the distinctly corrosive and even fraudulent effects of money, Honey. Patients cannot "prefer" UESWL based on cost or quality when they are not offered clear, truthful, and objective information concerning safety, cost, or alternatives. And quality standards can in fact be trusted only when clear, truthful, and objective information is achieved and communicated to the public.

The effect on the characteristics of a product or activity such as mobile UESWL service in this case, by allowing it to be evaluated exclusively or predominantly on commercial terms rather than by scientific, medical, altruistic obligation, is a grave and serious matter. Make no mistake; the commercialization process wrought with the self-serving economic reasoning that propels it alters the "product," and the soundness of medical reasoning for mobile UESWL service. There should be no sort of accepted common assumption that a hyper-inflated commercialization process does not affect an outcome or product such as UESWL on moral and medical terms. This would flagrantly insult the public's intelligence.

When we blindly permit market reasoning to replace tangible evidence of medical harm, we are placing our bets on the economic provision that a "free market" will simply act as it does and ultimately correct itself. Really? How on earth will the "free market" ever correct itself when sick and vulnerable patients receiving this market-tainted UESWL procedure are not provided even the slightest opportunity to know hard, critical facts about the harmful nature of this procedure? How will the "free market" ever correct itself if market-based reasoning prevents better treatment methods from being be used and/or newly developed? How will the "free market" ever correct itself when patients are not actually choosing any properly offered objective alternatives based on honest facts? How many thousands of people will be harmed while the urology community willfully conceals and callously ignores the inopportune fact and disturbing evidence that UESWL is not safe in favor of a lot of extra money? How many decades must pass?

At what measurable human cost will we permit them to continue fulfilling their argument for market reasoning? How many patients will "walk in" with a kidney stone, and "walk out" with diabetes, hypertension, a splenectomy, or renal failure instead? How will market reasoning deal with such mortal, moral implications, when patients may believe they are making therapeutic decisions with their urologists in good faith based on confirmed safety measures, when they may actually instead be unwittingly making significant life-altering, or life-and-death decisions due to critical facts undisclosed to them?

Adverse effects of UESWL have essentially never been voluntarily reported to the FDA. Therefore, safety oversight is effectively nonexistent for a procedure that still has not been proven safe! Is this what we mean by "freedom?" Achieving a thirty-year hiatus for responsibility to measure and report safety of UESWL has been accomplished by means that have been tribal, predatory, organized, and highly secretive in American urology. Billions of consumer healthcare dollars have by now been taken and used against the consumer in order protect the "freedom" of this outrageous under-the-radar plunder by these urologists and their market-forward "business managers."

Research shows that UESWL predisposes patients to diabetes, among other serious life-threatening conditions. Based on what was known about the trauma of this procedure and the "blast" path of the shockwave treatment, this is and was predictable. Diabetes is the leading cause of kidney failure, lower limb amputations, and new cases of adult blindness. It is a major cause of heart disease and stroke. Medical expenses for people are more than double for patients with diabetes than for those without diabetes. 67% of people with diabetes have concomitant hypertension. 60-70% of diabetics suffer nerve damage. Diabetics are more susceptible to life-threatening infections. Diabetes cuts of 8.5 more years of life off the average 50-year old with diabetes than the average 50-year old without diabetes. Diabetes costs the U.S. an estimated $174 Billion per year. Urologists are neither tracking nor reporting patients for such adverse effects. So, do kidney stone patients "prefer" UESWL and the risk for diabetes they otherwise may never suffer? Maybe we should ask them. Maybe we should be solving the diabetes epidemic rather than causing it.

If for example, a drug were prescribed for morning sickness that clearly proved to remedy morning sickness, but caused horrible teratogenic defects in women's fetuses, would that drug be considered safe? Or effective? If a drug were prescribed to readily remedy gastrointestinal ulcers, but also caused major bones to break ten years down the road, would that drug be considered safe? Or effective? Was Fen Phen safe? Or effective? If lithotripsy were performed to readily "pulverize" kidney stones, but caused diabetes, hypertension, renal failure, ruptured spleen, damaged pancreas, loss of functional renal volume, and death would that procedure be safe? Or effective? Is it even legal to withhold the facts of grave risk from a patient when the FDA has never proven safety of the procedure? It is not okay for it to be this way for UESWL and as

humans we know this. What is most disturbing is that the urologists also know this. It is their principal responsibility to know this.

Risk cannot be offset when the facts are carefully concealed by a cloistered one-sided market-based argument, especially over thirty years. Rather than working in a deliberate, concerted effort to devise treatment methods that CAN be determined to be safe, instead we have gotten every excuse in the book for deploying UESWL. Neglecting and hiding the medical facts about UESWL in favor of its commodification is morally outrageous, repugnant, and grotesque. UESWL has become the "moneyball" of medicine, at unfathomable cost to healthcare consumers kept in the dark.

After nearly thirty years of gravely consequent inattention to the medicine of UESWL in favor of its role in the marketplace, this has all gone desperately way too far. UESWL is a very easy "sell" to the patient population at large. It is "non-invasive," a term effectively bandied about to convey that which diminishes risk of harm. It is nearly as simple as that. Who would endure the risk of an "invasive" surgical procedure, when a kidney stone could effectively be "pulverized" and passed "non-invasively?" What a perfect tag line, "non-invasive."

But what patient would actually risk consenting to a "non-invasive" procedure if he knew the alternative "invasive" procedure would protect him against diabetes, hypertension, renal failure, and many other life-altering, harmful and deadly medical effects of UESWL? Patients are not choosing, because patients are not given the facts; their rights to choose have been severely abused. In the "let the buyer beware" marketplace, this might be okay, but in medicine for the sick and vulnerable it is not remotely okay, and the two should never be permitted to be confused. Any urologist's argument for UESWL "being the best technology we have now" is immaterial in absence of proper disclosure to patients for the dire risks posed by this procedure. It is a non-argument, because it is purely anecdotal.

Market-based reasoning does not concern itself with the medical facts when they conflict and you can otherwise hide them; no need for medical reasoning when the market-based argument is humming along nicely and no one is watching. We have seen this in other cases. Urologist "shareholders" in the massive national UESWL organized "Outfit" as here in Michigan, would in fact be acting against "shareholder" economic interest were they to subvert their roles as their company's producers in favor of applying judicious, scientific medical reasoning; wouldn't that breach their "shareholder" responsibilities? It would! Market based reasoning is concerned almost exclusively with how you manage to convincingly "sell" the "product," the medical facts be damned for the sake of improving "profitability." Besides, the thirty year absence of accountability in medical research permits them to claim just about anything at this point.

So the real question is this: What will it be: The market, or honest medicine? That this could even be such a conundrum demonstrates just how debased we have become. There

should never be any question or conflict between the full faith of honest medicine and the subversion of truth for corrupted market-based callous indifference. This is a matter of basic human decency, why we educate ourselves, and it is what separates us from the eat-or-be-eaten wild.

If the FDA were charged only with granting approval for effective technologies, we would be living in a very different world today. But it is their distinct obligation to the American people that technologies are both effective *and safe*. We, as voting citizens in a democracy have chosen efficacy *AND* safety. But again, in 1984 the FDA abdicated; practically speaking those authorities may even be dead by now, it has been so long ago. They passed their authority for learning the safety of UESWL over to the medical community of urologists in good faith, believing practicing urologists would report concerns and/or confirmations about safety risk back to them; they expected them to do the research. They didn't do it. After nearly thirty years, any trust the FDA might have had in urologists to competently and honestly raise vital concerns or lack thereof about UESWL safety has been badly violated. It is time to measure the cost of this serious breach of trust.

Simply taking money away from some and giving it to others doesn't cut it. Somewhere in the exchange, value must be established and met with a critical eye. So, what is the value of UESWL? If it does not include safety, just how valuable is this procedure? If it costs billions just to treat adverse effects of the procedure, just how valuable is this procedure? And who now is deciding on what merits the basis for value of UESWL is founded? Somewhere therein lies the core of its provision under principles of cost, quality, and access.

Were there to be no payments made until the proper research is completed to discern safety of UESWL, what do you predict might happen? Would medicine be the prevailing force for patient care, or would it remain based on the corrupted market forces in this case? Would a truly effective *AND* safe technology for kidney stones suddenly emerge in the marketplace? Somebody needs to call it; the jig is up and we must act.

We urge you to act in your utmost capacity and authority to decide that quality care must include clear provisions of *SAFETY* and *EFFICACY;* that access to UESWL become far more judicious, and that patient consent forms for CON approved service sites be submitted to MDCH CON for approval. UESWL is a procedure that has not been proven safe and should be very carefully monitored for harmful costs in both life and treasure. We urge you to consider advising MDCH to develop a public service program for kidney stone prevention in Michigan. We urge you to seek out talented Michigan engineers and scientists to find safe and effective technologic solutions for kidney stone removal; we must fix this diabolical problem.

Please help to find some other legitimate way to pay urologists to be clearly objective in their work; this whole disgraceful UESWL scheme must end. Please measure your

response to deploying UESWL delivery standards in the context of cost, quality, and access based on the facts, and not merely on market-based wishful thinking.

Thank you for your dedicated service.

Sincerely,

Anne Mitchell
US Citizen
Ae_mitchell@comcast.net

Cc: The Public

August 22, 2013

Via email

Michigan Department of Community Health
CON Commissioners
Certificate of Need Policy Section
c/o James B. Falahee, Jr., J.D.
Chair, CON Commission
201 Townsend Street
Lansing, Michigan 48913

Chairman Falahee and Distinguished Commissioners:

Thank you and the Certificate of Need Department for your dedicated commitment for cost effective access to quality healthcare in Michigan. This written testimony is intended as public comment for your September 17, 2013 meeting and for consideration during your analysis and discussion of UESWL standards in this critically important review period.

Kindly, first consider the money alone; $100,000,000.00. No joke, this is pretty beefy; it is a very conservative estimate over the past eight years for the amount Michigan healthcare consumers alone have paid ***in excess of direct costs*** for mobile lithotripters and UESWL technologists, regardless of CON oversight for cost, quality, and access to UESWL. In the United States over the past thirty years of urologist-syndicated UESWL "service," comparable excessive overpayment can easily be estimated at over $11,000,000,000.00.

Health Systems, urologists, syndicators, and insurance carriers have full knowledge of the excessive overpayment metrics of this outrageous scam; certainly we can all perform simple math. Patients, healthcare consumers, the people who paid this money, though, don't have a clue. Why are we allowing this heist? Really, why? Surely there is a clear, transparent explanation for this monumental thievery, so kindly oblige the people of Michigan with the tale, the truth, and the real story. We all deserve to hear a manner of valid explanation for this "free-for-all" spree that even we plebs can understand. Please explain the value and benefit we have received for the outrageous amount of money we've overpaid and day after day continue to spend on a traumatic procedure ***not proven to be safe***; it is time we are given the answers. What did healthcare consumers receive in concrete terms for their money? Where did this money go?

What if we'd spent this $100,000,000 on actual medical care instead of on kickbacks? Please give distinct consideration to the fact that these were real people's healthcare dollars; it is reasonable to expect they will actually be spent on healthcare, to cure disease, to improve health, and not spent on a frivolous roll of the dice played with people's lives so that the Outfit can succeed to realize the heist of the century. This is very, very serious.

In the past month, our NIH Director, Dr. Francis Collins, a man with substantial ties to Michigan, has allocated $96,000,000 for "Big Knowledge Data Centers;" this is one reasonable example for how $100,000,000 healthcare dollars could be spent. This recent NIH allocation is constructive by contrast, and perhaps Michigan could seek a little redemption and a piece of this prize. With its strong history and infrastructure already in place, MDCH and the CON Department could actually provide the kind of high quality data our nation desperately needs to clear a pathway for

combatting a national epidemic of costly, deadly kidney disease, for example; to actually help people.

How about it? Step forward! It could be a collaborative effort with arguably our country's finest institution for population research; the University of Michigan. Ya'll are right here in our midst. You could get organized to do this critically important work in healthcare that our nation's urologists refuse to do but that our country sorely needs. If we could just get to some honesty about how all this kidney disease is destroying so many lives at such astronomical cost, some clear answers, maybe medicine can begin to properly serve the sick again. And ya'll might actually be able to help stop the burning of money on B.S. What's more, perhaps then a far more transparent and honest means of getting urologists paid for their work might emerge.

If not me, who? Somebody needs to just get really indignant out here about the unbridled greed and the dishonest, malicious deception of urology syndicated UESWL. Decorum is just too insubstantial, and does not rise to meet the outrageousness of this national UESWL debacle. How, otherwise will we ever meet our distinct responsibilities to move critically important medicine forward? It is long time to get out of this lax, blinding, haze of a cover up for "this is how we do things," of "this is how we were trained," and of "how can we most effectively game the system and 'find a better way'?" My blistering rant here is an attempt to deliver an opposing equivalent response by measure against the in-your-face, outrageous, deceptive, malicious, shameful, deadly exploitation of the Outfit's UESWL scheme. This has gone way too far down a deadly road now, with the compass having been tossed out the window long ago, and we simply must reestablish proper moral and scientific navigation. It is the decent, human thing to do. It is time to start over on a much more honest and trustworthy path.

I can easily think of at least a hundred far, far more constructive ways of spending $100,000,000 consumer healthcare dollars on actual health and medical care. In my finger-wagging tirade, I'll be happy to list them at your request, and they will meet rigorous cost/quality/access measures. Real measureable progress in reducing healthcare spending must include fair and reasonable oversight and cooperation; far, far more than merely letting the so-called "free market" exploiters their freedom to "compete" for just burning up all our healthcare dollars often on extremely grotesque, dishonest, and irresponsible schemes like these UESWL syndicates while nobody watches with a critical eye or cares about anyone but themselves. Oversight is needed if only to simply keep them domesticated.

It is time to focus; the money spent and the medicine delivered in no way or form should be separated. So, follow the money; it is clearly the law of our land. When it appears too good to be true, just follow the money and you will undoubtedly find bad medicine attempting to hide underneath. Take IMRT for prostate cancer; it is also there. Nearly seventy percent of radiation-treated prostate cancers are failures. Why should we permit Medicare to pay $40,000 or more/treatment for such colossal failure? When 7 of 10 fail? Really? So that the Outfit's salvage prostate cryotherapy procedures can then back these radiation failures up later on at even more outrageous cost? The metrics of these strategic IMRT schemes, when the math is done, are even more outrageous than the UESWL scams. What on earth? It is blasphemous and grotesque, especially considering the additional adverse effects of IMRT, like burning holes in the rectums of old (and young) men; especially when there is more and more evidence that it may be entirely possible to prevent prostate cancer in the first place! Nothing like having a colostomy to go along with all that radiation in your golden years!

Honest and critically informed oversight is needed to stop burning our scarce healthcare dollars so that medicine can actually be incented to move forward and improve! It is always a good idea when something doesn't pass the "sniff" test, if your first gut reaction tends toward "this stinks," to remember this is cause enough to challenge assumptions of what appears superficially to be an entirely offensive, stinking-to-high-heaven practice – because below the ground it probably is!

Consider the outrageous size alone of the sophisticated bait and switch cover-up of UESWL's unproven safety in favor of the scheming Urology Outfit's pure economic interest. You must admit, it is impressive. Barely below the surface, their highly organized and ***distinctly proud effort*** funded entirely by extracting ordinary people's healthcare dollars that were intended to pay for "facility fees," and their unchecked power to level what turns out to be serious life and death consequences in the absence of adequate risk disclosure, totally eclipses their interest in or responsibility for the actual medicine of UESWL. No one is responsibly examining the vast amount of money spent on adverse consequences of UESWL; a deep, black, cause-and-effect hole borne of arrogance and hubris. It is hard to estimate the billions of healthcare dollars flushed down that deep, dark hole, and the hundreds of thousands of lives cast tragically into serious chronic disease or the looming threat thereof due to this deceptive scheme. The money has been placed entirely in front of the medicine, because placing the medical facts in front of the money would simply poison and kill the money tree! UESWL is not safe; proof of safety is anecdotal at best. Outing the harm of UESWL would be just too much of a nationwide buzz-kill at this point.

You must ask: Do healthcare consumers consent to this? Is this what they want? Is this what they need? Do kidney stone patients know that urologists are intentionally playing roulette in the shadows with their kidney function, pancreas/ diabetes, spleen, etc., for the money? Hardly! Never ever forget that the basic tenet of medicine at its root is morality, and that it is consent that should inform and guide every moral and therefore medical decision. Consent: Honest and complete disclosure. Consent for what precisely will be delivered at what cost, with clear, fair, honest, responsible, competent warning both for adverse effects and financial implications.

We have just been standing by and watching this? Blindly trusting and permitting the teaming up of doctors, lawyers, hospitals, businesses, legislators, governments and more in a sophisticated and ungodly scheme to deny science and medicine in a planned, deliberate, and calculated effort to extort consumers' healthcare dollars from the system? It is malicious, duplicitous exploitation. Not only is it incredibly disrespectful, but grotesquely shameful. I would argue it is distinctly criminal. It borders on reigning terror. It is time for the public to understand the truth.

There are no properly vetted guidelines for treating or retreating, for example, a 1.0 mm kidney stone versus a 5.0 mm stone – so no one is actually tracking anything about the safety, difference in outcomes, or adverse effects of one versus the other! No one is held to any relevant account of the facts. Actually, none of this is being tracked at all, regardless of the stone size, trauma and the evidence! The decision to perform UESWL is entirely between "a patient and their doctor." Nice, because that is really pretty damn convenient for the Outfit. As long as the urologist can convince the patient behind closed doors, then the sky's the limit, practically anything goes, and the Outfit continues to control and call the shots! After thirty years, no one yet is asking questions?! While the renal transplant lists just grow longer and longer and longer? The test-strip business is booming and that of *metformin* and *metroprolol*. "Business" is booming! And the $Billions just keep being pumped over to the UESWL masterminds. Each passing year the Outfit

turfs a little more grease to legislators to make sure the skids stay slippery. UESWL in the United States provides a simple primer in how to keep Joe Six-Pack in his place. Poor and useful Joe Six-Pack: blindfold him, take his money, his tax dollars, his health, and then poverty-stricken, make him suffer until he dies.

Here are merely three of the questions concerning patient safety that an urologist should be required to fully and honestly answer following treatment of any patient with UESWL:

- Do you know whether you have fully or partially destroyed the functionality of the treated kidney?
- Do you know whether you have damaged the patient's pancreas or to what extent the pancreas has been damaged during UESWL?
- Have you fully disclosed to the patient what it means to fully or partially destroy the functionality of his kidney or damage his pancreas in terms of the future of his life, health quality, and finances?

The answer to these three questions will be "no" if the urologist has answered honestly. Instead, we hear, "Oh, but for our highly trained technologists with "X" years of experience!" The Outfit's canned "trained technologist" answer has nothing to do with answering these highly critical questions about safety. It is not enough that a technologist merely knows how not to kill the patient on the table as a measure of safety, or attempt to minimize damage. What needs to be known is the **truth** of the damage that has happened during a treatment. **Urologists do not know, nor is there evidence they want to know**. Because they are mostly controlled by the Outfit. If the urologist does not know the truth and is honest instead about not knowing, these patients should be given full understanding of the consequences and provide their truly informed consent concerning life and treasure for this complete crap shoot. Which begs the real questions: Where are the ***real*** statistics? Why are we allowing this? Are the alternatives much safer by comparison overall? Why on earth after thirty years don't we know?

Consent for the Outfit would look something like, "*Though I will make best efforts given the circumstances, today you are consenting to a procedure which may destroy or badly damage your kidney or pancreas. Other damage may also happen to your spleen, lung, arteries, etc., etc. Or you could die. Do you know what this means? If you live, it is entirely possible for the rest of your life that your medical expenses will be doubled, tripled, quadrupled, or more, and you may suffer a significantly poorer quality of life. Not knowing facts about UESWL likely costs the healthcare system hundreds of billions of dollars. UESWL is effective for breaking kidney stones. It also can badly damage or destroy vital organs, we just don't know, because the safety of UESWL even after thirty years of utilization in the United States has not been adequately researched on purpose. It is important to me, more than knowing the actual safety statistics of UESWL for you, that I have found a better way to make an extra $1500.00 or so more than my professional fee today by treating you with UESWL rather than alternative methods.*"

I challenge any one of you to find one healthcare consumer or kidney stone patient who with full knowledge would consent to this UESWL heist on moral, medical, and financial terms given the facts. But the Outfit wants us to believe the facts are inconsequential, so they strive to hide them as anecdotes. Don't you think proving UESWL is what they say it is would be their obvious road

to redemption? So why doesn't the Outfit do it? With the millions they otherwise pay lobbyists, perhaps? Nothing valuable or actionable is in the medical literature on purpose. Nothing. Imagine the serious quality issues in all the variable and uncontrolled environments; have UESWL technologists ever once seen the physical harm they've caused a treated kidney or pancreas? Does one urologist out there have any knowledge whatsoever if he's caused damage enough to any one patient's pancreas via UESWL to cause their diabetes? **No** is the answer.

These adverse effects are not merely intriguing, fascinating, interesting anecdotes up for endless decades of discussion in the medical literature. They are about real people's lives! Why aren't the questions being asked? Shouldn't we require these answers in every case? What about hypertension caused by UESWL? It is entirely possible that for any given treatment, the functionality of the treated kidney may be entirely destroyed and the patient would never have any way of knowing… until it crept up later, insidiously. Isn't it a distinct ethical obligation to forewarn all patients of the research urologists have refused to do for thirty years prior to consenting to UESWL? What on earth are they doing? And why are we letting them get away with it? If cause and effect of UESWL is never defined, we're toast. A patient was killed outright in Michigan with UESWL; no one ever reported it to the FDA.

Critical knowledge of the history and facts concerning UESWL has been deliberately ignored by the Outfit, and in Michigan perhaps due in small part to the complacency coming from nearly thirty long years (yawn) performing the procedure under CON. You've been sold a bill of goods and your eyes have been taken off the ball. You've been turned by the oldest, slickest marketing trick in the book; that is, you've been made to focus on the money and not on the product. It takes minimal skill by salesmen to draw attention away from the product itself in order to focus you entirely on the exchange of money instead. They have magically created value where there is none. If you do not see what the product is actually doing, then it appears on the surface to be six of one, half a dozen of another. Marketing, enterprise, but this is **not medicine**.

Safety of UESWL is unproven. Period. Think; just how has it happened for healthcare consumers to have paid out an extra $11,000,000,000.00 dollars in this country and $100,000,000.00 in Michigan to urologist-owned syndicates for a procedure that has not been proven safe? Do you think it might just be the tap-dancing-we-have-trained-technologists, money-grubbing "market" incentive that ensures UESWL will never become proven by the data to be unsafe? It is time to get to the bottom of this by putting eyes back *on* the ball. Just who else is getting greased by this abusive scheme? You will find out if you will only follow the money.

Healthcare consumers deserve the performance bar to be raised here to at least a reasonable trustworthy standard, but this will require more participation from informed overseers, not less. CON especially today is critically important to healthcare, so long as money is not blindly separated from the medicine; it can be a tremendously effective means for vastly diminishing massive waste and fraud. In the case of UESWL it will mean saving people's lives. I cannot think of a more important time in medicine for there to be a pro-active, constructive CON Department with far more critical authority to focus on cost and quality by clearly analyzing clinical data. Recently, it was shown, for example, that one (1) PET scan performed at the right time is as predictive as five (5) PET scans performed in a prescribed follow-up period, though more research is needed. Without public oversight, the same kinds of incentives remain today that will keep healthcare costs in an uncontrolled spiral, regardless of ACO's. Nothing could be more important now than a reinvigorated, hearty, discriminating CON process and rigorous,

formative healthcare debate. Nothing could be more important now than connecting the money to the medicine. Public health systems need some real rocket fuel to bring us out of the harmful, wasteful financial mess that has been so prevalent in healthcare delivery for far too long.

If a procedure or process doesn't work, why should healthcare consumers pay for it? Why? What's it worth? Even more so, if it causes grave harm, why should healthcare consumers pay? Highly measurable cost savings depend on connecting real dollars to the actual medical value of any given diagnosis or treatment. Imagine, for instance, what happens *outside* a CON process when even within a CON process a quick and easy $100,000,000 and sacred medical trust for safe care can so easily be heisted from the public.

Now to the dirty little secret in medicine: ***Statistical Significance.*** Those of you here like me with research backgrounds completely understand the clarion call of statistical significance. Every medical doctor has implicit and thorough understanding of the importance of statistical significance; and when you do, you also easily recognize when it is obvious that intentional absence of necessary research represents dodging of a bullet. It is ***the*** bullet. It proves. It disproves. And when sidelined, absence of statistical significance permits absolutely nothing to be demonstrated, creating a convenient "Limbo-land." Limbo-land is the cowardly place to hide when you clearly, obviously find a problem you don't want to solve with an answer. It is the filthiest secret in medical research, holds us back, and disregarded for UESWL over thirty years while brazenly mocking patient safety, absence of statistical significance in favor of anecdotal tidbits concerning grave safety hazards has permitted billions of dollars to be siphoned over to the Outfit's urologist-syndicated "joint ventures." Limbo-land can kill people. For the money, one could hide in Limbo-land forever. It has given a level of power to urologists to sideline and neglect their distinct responsibilities to do no harm now for decades. How clever, and how evil.

The Outfit's carefully crafted magic sleight of hand has created a cheesy, shifty optical illusion in plain sight. Power consolidated out of the money they've heisted has fostered the kind of blinding haze for us to have trusted them and stood idly by for decades, while their defensive legal teams first constructed, then successfully lobbied, defended and upheld the deceptive UESWL joint venture "structures" for them. Using our healthcare dollars, this tactic was successfully deployed to divert attention away from the obvious, frightening truth behind the medicine being practiced within these "joint ventures." Highly organized, politically engaged, very well-greased urologists have been given carte blanche over thirty years to deploy UESWL without proof, disclosure, clear patient safety or critical follow-up guidelines. They've used the patients' heisted healthcare dollars to pay for policies to support and protect the heist. The cost to the public in life and treasure, to the "tax payer" of this is unimaginably massive.

Healthcare dollars not actually spent on the care intended by consumers spending the money has instead purchased urologists' ability to hide this dangerous standard of care behind a black curtain of anecdotes, and intentional, frightening neglect. Fully aware of the distinct problems, urologists have had complete power and great reason to take UESWL technology seriously, respect its failings, to conduct the straightforward work to prove its safety in patients, or to simply engage the FDA. But they've refused in obvious attempt to protect their own personal financial interests. Clear evidence of the nature of grave harm from this extremely poorly researched standard of care, entirely devoid of proof from an even remotely statistically significant body of research for safety over more than a generation, is long overdue and must be addressed now. Not knowing is dishonest and far too harmful. After nearly thirty years, time is up; enough is enough.

When obvious harm being done cannot routinely or obviously be predicted because the knowledge base is kept hidden, unknown, and protected within a well-funded national secret society of urologists, and where no appropriate follow-up testing is required in clear consideration of the potential for serious harm, government must step in to protect the public. There can be only one motivation for heinous, deliberate neglect to achieve evidence of statistical significance in the face of an obvious need to establish safety of this procedure after thirty years; MONEY. It is outrageous and deeply shameful. A few pretty pictures of pathologic kidneys do not tell any story whatsoever, so don't bother. Just follow the money and you will find the Outfit.

With cunning and sophistication, and a spin machine funded by money that was otherwise intended to have been spent on healthcare, the Outfit has permitted urologists, without financial risk, to conspire for nearly thirty years within their own trumped up consent decree and prosper in cooperatives by trafficking UESWL in a game of human rendition as if it were merely an element of some business balance sheet from a hedge fund. The Outfit's hedge fund where urologists perform the business functions, pull all the strings, and behave as combinations of CEO, CFO, risk officer, and medical practitioner, while betting their futures against the futures of their patients' lives. A hedge fund where they will continually win because of a merger with government officials that permits them never to disclose the significance of the danger they pose to hundreds of thousands of unassuming lives in order to keep the $$Billions flowing in and out. Follow the money; where it is coming from and where it is going. Then ask if human life matters.

When we trade truth, science, and medicine in favor of gamesmanship, politics, jockeying, lobbying, marketing, stealth and pure extortion, we lose any credibility whatsoever as standard bearers of science and medicine, or law for that matter. This has happened; we are here now and all the evidence and facts bear it out. Being a standard bearer first requires having standards in the first place. We are far better and smarter than this. In the words of President George Washington, "Let us raise a standard to which the wise and honest can repair…" We, here, together are responsible for permitting an outrage such as UESWL syndication to happen and it is long time to restore honesty and trust. It is time to reconcile accounts. It is time to require proof. It is time to stop burning the money. We cannot afford nor should we ever tolerate amoral treachery in medicine. This is not okay. It is long overdue to do the right thing by asking the right questions and taking action.

Here is a snippet for your pure entertainment of how the sick Outfit spins it in the case of *Endocare (Healthtronics)*, for example. Regardless of which faction, *AKSM, UMS, UST, Council on Urological Interests, Endo*, or whomever within the *Outfit*, it is textbook execution of the scheme. *Healthtronics* describe themselves in this way, *"HealthTronics was conceived over 25 years ago by a group of urologists looking for a better way. They discovered that partnerships and specialization helped everyone run a thriving, successful practice. While we have grown and added services, our focus has not changed, we have remained a company committed to the urology community."* Sounds like a harmless sound bite on the surface, "*looking for a better way*." Read between the lines – they found a better way, alright; but, certainly not by practicing medicine. Instead it was by plundering billions of healthcare dollars that had been designated to be spent on actual medical care, and by disrespecting untold numbers of lives. *"A better way."*

You've seen the *"AKSM Urology PAC."* Now meet the *"Endo PAC,"* draped oh-so-beautifully in the Stars and Stripes as a beacon of their "freedom," and see just how it is that the American

people, their hard earned healthcare dollars, and their freedom have been taken, hook, line, kidneys and pancreas as bait:

http://www.endo.com/File%20Library/About%20Us/Endo-2012-Annual-PAC-Contributions-Report_041813.pdf

You'll find Michigan's own Fred Upton on Page 7 of this juicy report. In 2012, the good Congressman Upton was fed his portion of the blood money by *Endo PAC*, while fulfilling his duty as others have described; "Upton has been recognized by Grover Norquist's Americans for Tax Reform as a "Hero of the Taxpayer" and by the U.S. Chamber of Commerce with the "Spirit of Enterprise" award." You betcha. And he's "pro-life" to boot! Sure.

In 2012, Endo paid a total of approximately $3.86 million for direct lobbying, approximately $2.21 million of which was at the federal level and approximately $1.65 million of which was at the state level. Endo paid a total of approximately $417,000 in indirect lobbying expenses in 2012. *Let me reiterate: these were consumers' healthcare dollars that were otherwise designated to have been spent on healthcare*. Do you think it mattered to the good Mr. Upton that he was paid consumer healthcare dollars sucked out of the system that were meant to have been spent on healthcare, and that he received this to keep the Outfit in the business of plundering American kidney function? Does Mr. Upton really care one way or another as long as his coffers are filled? Perhaps the good Congressman Upton will take action to support outsourcing of the creation of all this renal failure to Mexico as well! Perhaps we should designate Upton instead as "Hero of American Kidney Failure." Unfortunately for Joe Six-Pack, Congressman Upton is not the only one. Maybe we just need a new "Joe Six-*PAC* to counter with *anti*-blood money."

According to Endo, "There's always going to be a better way." Yep, we have that to look forward to: "*At Endo Health Solutions, we operate under a common set of guiding principles that enable us to provide quality products that serve unmet patient needs. Those principles allow us to focus on solutions for everyone in the healthcare continuum. Physicians want better solutions. Patients want to get better. Payers want a reliable financial model. Endo's collaborative, customer-driven approach enables employees to see a need, craft a solution and find a better way to guide our customers.*" Read between the lines. Connect the terrorizing dots. Just imagine what they are capable of figuring out next.

This is a very serious life and death matter. Please exercise your authority by taking broad and factual understanding of UESWL and all its contrasting bounty and measly anecdote into account, and enact standards for UESWL delivery with proper perspective concerning patient health, safety, disclosure, and cost. Those who can do something must. I urge you to raise the bar and help us, and not to feed the beast as party to this human disaster.

Thank you for your dedicated service to Michigan healthcare, and for withstanding yet another of my very indignant but deeply sincere pleadings.

Sincerely,

Anne Mitchell
Ae_mitchell@comcast.net

11:CV-10090

HON VICTORIA ROBERTS

UESWL Survey Data for 2008:

Facility No.	Type	Facility Name:	# Units	# Procedures	# Retreats
82M103	M	Ford & Harper Mobile Lithotripsy	2	1,959	25
33M147	M	Great Lakes Lithotripsy	1	1,236	9
33M023	M	Great Lakes Lithotripsy, LLC	2	2,112	46
33M074	M	Great Lakes Lithotripsy, LLC	1	1,533	8
99M167	M	Greater Michigan Lithotripsy	1	1,060	105
41M165	M	Spectrum Health – Butterworth	1	1,066	125
63M164	M	William Beaumont Hospital	1	1,013	91
TOTAL			9	9,979	409

Volume Requirement for Expansion

The Department received testimony from one (1) organization requesting that the volume requirement for expansion be lowered.

Section 8(1) of the Standards, requires that all of the applicant's existing UESWL units (both fixed and mobile) at the same geographic location as the proposed additional UESWL unit, performed an average of at least 1,800 procedures per UESWL until during the most recent 12-month period for which the Department has verifiable data.

In looking at the 2008 survey data, none of the nine (9) CSCs would meet the current volume requirement for expansion. For the most part, all are doing on average 1,000 procedures a year per unit.

The Department received testimony from one (1) organization that cited that their management company, American Kidney Stone Management, Ltd. (AKSM) reviewed case load to determine typical volume rates for the AKSM mobile lithotripters. The testimony provided the following facts based on what they found out from AKSM: on a nationwide average, a mobile lithotripter performed 600 cases per year. In addition, the minimum number of cases performed on any single mobile lithotripter is 1,200 cases. Lastly, they state that once volume exceeds 1,000 cases per lithotripter, a second mobile unit is added to the mobile route. The testimony goes on to state the reasoning behind this is that after a second lithotripter is added to a route the overall volume increases. A single mobile lithotripter that treats more than 1,000 cases annually is subject to

2009 Michigan Certificate of Need Annual Survey
Lithotripsy (UESWL) and Percutaneous Nephrostomy Services - Host Sites
Report 090

47.0020	ST. JOSEPH MERCY LIVINGSTON HOSPITAL	H	73	0
50.0060	MOUNT CLEMENS REGIONAL MEDICAL CENTER	H	101	6
50.0110	HENRY FORD MACOMB HOSPITAL	H	138	0
50.6846	UTICA SURGERY AND ENDOSCOPY CENTER	F	170	0
63.0014	HURON VALLEY-SINAI HOSPITAL	H	114	0
63.0050	BOTSFORD HOSPITAL	H	121	0
63.0120	POH MEDICAL CENTER	H	64	0
63.0160	WILLIAM BEAUMONT HOSPITAL, TROY	H	181	0
63.0177	PROVIDENCE MEDICAL CENTER-PROVIDENCE PAR	H	455	0
63.6923	LAKES SURGERY CENTER	F	44	0
74.0020	PORT HURON HOSPITAL	H	56	12
81.0030	ST. JOSEPH MERCY ANN ARBOR HOSPITAL	H	145	0
81.0080	CHELSEA COMMUNITY HOSPITAL	H	60	0
82.0030	WILLIAM BEAUMONT HOSPITAL, GROSSE POINTE	H	99	4
82.0120	OAKWOOD HOSPITAL AND MEDICAL CENTER	H	420	0

The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section B of the survey.

2009 Michigan Certificate of Need Annual Survey
Lithotripsy (UESWL) and Percutaneous Nephrostomy Services - Host Sites
Report 090

82.0190	ST. MARY MERCY LIVONIA HOSPITAL	H	105	1
82.6815	UNIVERSITY OF MICHIGAN SURGERY CENTER	F	104	0
83.0220	HARPER UNIVERSITY HOSPITAL	H	53	1
83.0450	SINAI-GRACE HOSPITAL	H	49	0
HSA 1: SOUTHEAST MICHIGAN	37 Facilities		4,979	120
33.0020	INGHAM REGIONAL MEDICAL CENTER	H	156	0
38.0010	ALLEGIANCE HEALTH	H	307	17
HSA 2: MID-SOUTHERN	4 Facilities		1,459	41
11.6055	CENTER FOR OUTPATIENT SERVICES	F	22	0
39.0010	BORGESS MEDICAL CENTER	H	215	4
HSA 3: SOUTHWEST	5 Facilities		473	7
41.0060	METROPOLITAN HOSPITAL	H	141	5
53.0010	MEMORIAL MEDICAL CENTER OF WEST MICHIGAN	H	60	2
61.0020	MERCY HEALTH PARTNERS - MERCY CAMPUS	H	154	0
70.0010	NORTH OTTAWA COMMUNITY HOSPITAL	H	16	0
HSA 4: WEST MICHIGAN	9 Facilities		1,453	53

The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section B of the survey.

2009 Michigan Certificate of Need Annual Survey
Lithotripsy (UESWL) and Percutaneous Nephrostomy Services - Host Sites
Report 090

25.0072	GENESYS REGIONAL MEDICAL CENTER	H	811	0
44.0010	LAPEER REGIONAL MEDICAL CENTER	H	84	3
HSA 5: GENESEE-LAPEER-SHIAWASSEE	5 Facilities		1,771	3
32.0020	HURON MEMORIAL HOSPITAL	H	22	0
73.6811	ST. MARY'S OF MICHIGAN TOWNE CENTRE	F	248	3
HSA 6: EAST CENTRAL	5 Facilities		419	29
24.0030	NORTHERN MICHIGAN REGIONAL HOSPITAL	H	134	0
HSA 7: NORTHERN LOWER	3 Facilities		383	0
52.0050	MARQUETTE GENERAL HEALTH SYSTEM	H	17	0
HSA 8: UPPER PENINSULA	3 Facilities		64	0
State Total	71 Facilities		11,001	253

The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section B of the survey.

2010 Michigan Certificate of Need Annual Survey
Lithotripsy (UESWL) and Percutaneous Nephrostomy Services - Host Sites
Report 090

47.0020	ST. JOSEPH MERCY LIVINGSTON HOSPITAL	H	81	0
50.0060	MOUNT CLEMENS REGIONAL MEDICAL CENTER	H	125	5
50.0110	HENRY FORD MACOMB HOSPITAL	H	92	0
58.0030	MERCY MEMORIAL HOSPITAL	H	206	0
63.0030	WILLIAM BEAUMONT HOSPITAL, ROYAL OAK	H	496	61
63.0070	CRITTENTON HOSPITAL MEDICAL CENTER	H	27	14
63.0110	DOCTORS' HOSPITAL OF MICHIGAN	H	45	0
63.0140	ST. JOSEPH MERCY OAKLAND HOSPITAL	H	227	32
63.0176	HENRY FORD WEST BLOOMFIELD HOSPITAL	H	72	0
63.6913	UNASOURCE SURGERY CENTER	F	13	0
74.0020	PORT HURON HOSPITAL	H	68	11
81.0030	ST. JOSEPH MERCY ANN ARBOR HOSPITAL	H	152	0
81.0060	UNIVERSITY OF MICHIGAN HOSPITALS	H	207	162
82.0010	OAKWOOD ANNAPOLIS HOSPITAL	H	160	0
82.0040	HENRY FORD COTTAGE HOSPITAL	H	65	0

The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section B of the survey.

2010 Michigan Certificate of Need Annual Survey
Lithotripsy (UESWL) and Percutaneous Nephrostomy Services - Host Sites
Report 090

82.0170	OAKWOOD SOUTHSHORE MEDICAL CENTER	H	227	0
82.0190	ST. MARY MERCY LIVONIA HOSPITAL	H	0	0
82.0230	HENRY FORD WYANDOTTE HOSPITAL	H	288	3
82.0250	UNIVERSITY OF MICHIGAN SURGERY CENTER	H	0	0
83.0190	HENRY FORD HOSPITAL	H	251	46
83.0220	HARPER UNIVERSITY HOSPITAL	H	0	0
83.0420	ST. JOHN HOSPITAL & MEDICAL CENTER	H	3	0
83.0480	SINAI-GRACE HOSPITAL	H	0	0
HSA 1: SOUTHEAST MICHIGAN	38 Facilities		5,517	372
33.0020	INGHAM REGIONAL MEDICAL CENTER	H	0	0
33.0060	EDWARD W SPARROW HOSPITAL	H	840	34
46.0010	ASSUMPTION HEALTH	H	0	0
46.0020	EMMA L. BIXBY MEDICAL CENTER	H	106	0
HSA 2: MID-SOUTHERN	4 Facilities		1,462	55
11.0070	LAKELAND HOSPITAL, NILES	H	5	0
11.0085	CENTER FOR OUTPATIENT SERVICES	H	0	0
13.0031	BATTLE CREEK HEALTH SYSTEM	H	170	0
39.0010	FORBESS MEDICAL CENTER	H	0	0
39.0020	BRONSON METHODIST HOSPITAL	H	53	0
HSA 3: SOUTHWEST	5 Facilities		472	5
41.0040	SPECTRUM HEALTH BUTTERWORTH HOSPITAL	H	659	32
41.0060	METROPOLITAN HOSPITAL	H	0	0
41.0080	SAINT MARY'S HEALTH CARE	H	77	19
53.0010	MEMORIAL MEDICAL CENTER OF WEST MICHIGAN	H	0	0
61.0010	MERCY HEALTH PARTNERS - HACKLEY CAMPUS	H	159	0
61.0020	MERCY HEALTH PARTNERS - MERCY CAMPUS	H	0	0
67.0021	SPECTRUM HEALTH REED CITY HOSPITAL	H	55	0
70.0010	NORTH OTTAWA COMMUNITY HOSPITAL	H	0	0
70.0020	HOLLAND HOSPITAL	H	83	6
HSA 4: WEST MICHIGAN	9 Facilities		1,423	72

The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section B of the survey.

2010 Michigan Certificate of Need Annual Survey
Lithotripsy (UESWL) and Percutaneous Nephrostomy Services - Host Sites
Report 090

25.0050	MCLAREN REGIONAL MEDICAL CENTER	H	730	2
25.6821	THE SURGERY CENTER-GENESEE COUNTY	F	316	0
78.0010	MEMORIAL HEALTHCARE	H	60	0
HSA 5: GENESEE-LAPEER-SHIAWASSEE	5 Facilities		1,883	4
09.0050	BAY REGIONAL MEDICAL CENTER	H	66	0
32.0020	HURON MEMORIAL HOSPITAL	H	21	0
73.6811	ST. MARY'S OF MICHIGAN TOWNE CENTRE	F	250	0
HSA 6: EAST CENTRAL	6 Facilities		455	15
24.0030	NORTHERN MICHIGAN REGIONAL HOSPITAL	H	189	0
84.0010	MERCY HOSPITAL	H	41	0
HSA 7: NORTHERN LOWER	4 Facilities		482	0
22.0020	DICKINSON COUNTY HEALTHCARE SYSTEM	H	25	0
52.0051	BELL MEMORIAL HOSPITAL	H	3	0
HSA 8: UPPER PENINSULA	3 Facilities		45	0
State Total	74 Facilities		11,739	523

The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section B of the survey.

2011 Michigan Certificate of Need Annual Survey
Lithotripsy (UESWL) and Percutaneous Nephrostomy Services - Host Sites
Report 090

47.0020	ST. JOSEPH MERCY LIVINGSTON HOSPITAL	H	1	63	0	0
50.0020	HENRY FORD MACOMB HOSPITAL - WARREN CAMP	H	1	106	17	0
50.0070	ST. JOHN MACOMB-OAKLAND HOSP (MACOMB)	H	1	104	0	0
50.6846	UTICA SURGERY AND ENDOSCOPY CENTER	F	1	456	0	0
58.6815	SURGICAL INSTITUTE OF MONROE	F	1	35	0	0
63.0030	WILLIAM BEAUMONT HOSPITAL, ROYAL OAK	H	1	423	25	74
63.0070	CRITTENTON HOSPITAL MEDICAL CENTER	H	2	134	16	14
63.0120	POH MEDICAL CENTER	H	1	56	1	0
63.0160	WILLIAM BEAUMONT HOSPITAL, TROY	H	2	138	21	6
63.0177	PROVIDENCE MEDICAL CENTER-PROVIDENCE PAR	H	1	482	61	0
74.0020	PORT HURON HOSPITAL	H	1	56	8	13
81.0030	ST. JOSEPH MERCY ANN ARBOR HOSPITAL	H	1	84	0	0
81.0080	CHELSEA COMMUNITY HOSPITAL	H	1	79	3	0
82.0030	WILLIAM BEAUMONT HOSPITAL, GROSSE POINTE	H	1	95	21	14
82.0120	OAKWOOD HOSPITAL AND MEDICAL CENTER	H	1	427	51	0

The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section B of the survey.

2011 Michigan Certificate of Need Annual Survey
Lithotripsy (UESWL) and Percutaneous Nephrostomy Services - Host Sites
Report 090

82.0190	ST. MARY MERCY LIVONIA HOSPITAL	H	1	110	9	0
82.0230	HENRY FORD KANOTEX HOSPITAL					
82.6815	UNIVERSITY OF MICHIGAN SURGERY CENTER	F	1	118	6	0
83.0150	HENRY FORD HOSPITAL					
83.0220	HARPER UNIVERSITY HOSPITAL	H	1	57	0	9
83.0450	SINAI-GRACE HOSPITAL					
HSA 1: SOUTHEAST MICHIGAN	36 Facilities		38	5,555	533	314
33.0010	INGHAM REGIONAL MEDICAL CENTER					
33.0060	EDWARD W SPARROW HOSPITAL	H	1	763	222	0
33.0810	ALLEGIANCE HEALTH					
46.0020	EMMA L. BIXBY MEDICAL CENTER	H	1	132	18	0
HSA 2: MID-SOUTHERN	4 Facilities		4	1,436	322	19
11.0070	LAKELAND HOSPITAL, NILES	H	1	10	0	0
11.6816	CENTER FOR OUTPATIENT SERVICES					
13.0031	BRONSON BATTLE CREEK HOSPITAL	H	1	140	2	14
39.0010	BORGESS MEDICAL CENTER					
39.0020	BRONSON METHODIST HOSPITAL	H	1	62	0	0
39.6811	HEALTHCARE MIDWEST SURGERY CENTER					
HSA 3: SOUTHWEST	6 Facilities		6	522	30	25
41.0040	SPECTRUM HEALTH BUTTERWORTH HOSPITAL					
41.0060	METROPOLITAN HOSPITAL	H	1	177	16	13
41.0080	SAINT MARY'S HEALTH CARE					
53.0010	MEMORIAL MEDICAL CENTER OF WEST MICHIGAN	H	1	103	6	0
61.0010	MERCY HEALTH PARTNERS - HACKLEY CAMPUS					
61.0020	MERCY HEALTH PARTNERS - MERCY CAMPUS	H	1	144	7	0
61.6817	MUSKEGON SURGERY CENTER					
67.0021	SPECTRUM HEALTH REED CITY HOSPITAL	H	1	12	0	0
70.0010	NORTH OTTAWA COMMUNITY HOSPITAL					
70.0020	HOLLAND HOSPITAL	H	1	112	3	14
HSA 4: WEST MICHIGAN	10 Facilities		10	1,422	89	74

The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section B of the survey.

2011 Michigan Certificate of Need Annual Survey
Lithotripsy (UESWL) and Percutaneous Nephrostomy Services - Host Sites
Report 090

25.0050	MCLAREN REGIONAL MEDICAL CENTER	H	1	696	226	1
25.6821	THE SURGERY CENTER-GENESEE COUNTY	F	2	376	128	0
78.0010	MEMORIAL HEALTHCARE	H	1	64	14	0
HSA 5: GENESEE-LAPEER-SHIAWASSEE	5 Facilities		6	1,916	586	1
09.0050	BAY REGIONAL MEDICAL CENTER	H	1	61	0	0
32.0020	HURON MEMORIAL HOSPITAL	H	1	7	2	0
56.0020	MIDMICHIGAN MEDICAL CENTER-MIDLAND	H	1	65	4	12
73.6812	MACKINAW SURGERY CENTER	F	1	2	0	0
HSA 6: EAST CENTRAL	7 Facilities		7	576	56	12
20.0020	MERCY HOSPITAL - GRAYLING	H	1	67	12	0
28.6173	NORTHWEST MICHIGAN SURGERY CENTER	F	1	249	5	0
84.0010	MERCY HOSPITAL	H	1	58	0	0
HSA 7: NORTHERN LOWER	5 Facilities		5	551	48	0
22.0020	DICKINSON COUNTY HEALTHCARE SYSTEM	H	1	35	0	0
52.0051	BELL MEMORIAL HOSPITAL	H	1	2	1	0
HSA 8: UPPER PENINSULA	3 Facilities		3	94	1	14
State Total	76 Facilities		79	12,072	1,665	459

The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section B of the survey.

2012 Michigan Certificate of Need Annual Survey
Lithotripsy (UESWL) and Percutaneous Nephrostomy Services - Host Sites
Report 090

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
47.0020	ST. JOSEPH MERCY LIVINGSTON HOSPITAL	H	1	28	1	0
47.5806	BRIGHTON IMAGING CENTER, LLC	F	1	10	0	0
50.0060	MCLAREN MACOMB	H	1	173	32	4
50.0070	ST. JOHN MACOMB-OAKLAND HOSP (MACOMB)	H	1	74	0	0
50.0110	HENRY FORD MACOMB HOSPITAL	H	1	118	9	15
50.5806	MESCA SURGERY AND ENDOSCOPY CENTER	F	1	10	0	0
58.0030	MERCY MEMORIAL HOSPITAL	H	1	130	9	0
58.5810	SURGICAL INSTITUTE OF MONROE	F	1	10	0	0
63.0014	HURON VALLEY-SINAI HOSPITAL	H	1	67	4	0
63.0030	WILLIAM BEAUMONT HOSPITAL - ROYAL OAK	H	1	0	0	0
63.0050	BOTSFORD HOSPITAL	H	1	132	14	0
63.0070	CRITTENTON HOSPITAL MEDICAL CENTER	H	1	76	0	0
63.0080	ST. JOHN MACOMB-OAKLAND HOSP (OAKLAND)	H	1	144	6	0
63.0120	MCLAREN OAKLAND	H	1	0	0	0
63.0140	ST. JOSEPH MERCY OAKLAND HOSPITAL	H	1	135	9	15
63.0160	WILLIAM BEAUMONT HOSPITAL - TROY	H	1	0	0	0
63.0176	HENRY FORD WEST BLOOMFIELD HOSPITAL	H	1	116	17	0
63.0177	PROVIDENCE MEDICAL CENTER-PROVIDENCE PARK	H	1	0	0	0
63.6923	LAKES SURGERY CENTER	F	1	99	6	0
63.6928	NOVI SURGERY CENTER	F	1	0	0	0
63.6936	CLARKSTON SURGERY CENTER	F	1	28	0	0
74.0020	PORT HURON HOSPITAL	H	1	0	0	0
74.6818	LAKESHORE SURGERY CNTR	F	1	39	1	0
81.0030	ST. JOSEPH MERCY ANN ARBOR HOSPITAL	H	1	0	0	0
81.0080	CHELSEA COMMUNITY HOSPITAL	H	1	84	0	0
81.0810	OAKWOOD ANNAPOLIS HOSPITAL	H	1	0	0	0
82.0030	WILLIAM BEAUMONT HOSPITAL, GROSSE POINTE	H	1	89	10	5
82.0040	HENRY FORD COTTAGE HOSPITAL	H	1	0	0	0
82.0120	OAKWOOD HOSPITAL AND MEDICAL CENTER	H	1	411	47	0
82.0170	OAKWOOD SOUTHSHORE MEDICAL CENTER	H	1	0	0	0

The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section B of the survey.

2012 Michigan Certificate of Need Annual Survey
Lithotripsy (UESWL) and Percutaneous Nephrostomy Services - Host Sites
Report 090

82.0190	ST. MARY MERCY LIVONIA HOSPITAL	H	1	146	16	1
82.6815	UNIVERSITY OF MICHIGAN SURGERY CENTER	F	1	106	3	0
83.0190	HENRY FORD HOSPITAL	H	1	299	35	28
83.0450	SINAI-GRACE HOSPITAL	H	1	35	3	58
HSA 1: SOUTHEAST MICHIGAN	37 Facilities		39	5,586	531	234
33.0020	MCLAREN - GREATER LANSING	H	1	124	12	0
33.6815	MICHIGAN SURGICAL CENTER	F	1	23	2	0
38.0010	ALLEGIANCE HEALTH	H	1	283	53	16
HSA 2: MID-SOUTHERN	6 Facilities		6	1,415	275	67
11.6055	CENTER FOR OUTPATIENT SERVICES	F	1	94	4	0
39.0010	BORGESS MEDICAL CENTER	H	1	195	15	8
39.6811	HEALTHCARE MIDWEST SURGERY CENTER	F	1	81	1	0
HSA 3: SOUTHWEST	6 Facilities		6	526	25	26
41.0040	SPECTRUM HEALTH BUTTERWORTH HOSPITAL	H	1	758	39	52
41.0080	SAINT MARY'S HEALTH CARE	H	1	53	1	46
61.0010	MERCY HEALTH PARTNERS - HACKLEY CAMPUS	H	1	135	10	0
61.6817	MUSKEGON SURGERY CENTER	F	1	62	1	0

The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section B of the survey.

2012 Michigan Certificate of Need Annual Survey
Lithotripsy (UESWL) and Percutaneous Nephrostomy Services - Host Sites
Report 090

70.0010	NORTH OTTAWA COMMUNITY HOSPITAL	H	1	64	0	0
HSA 4: WEST MICHIGAN	10 Facilities		10	1,500	88	155
25.0072	GENESYS REGIONAL MEDICAL CENTER	H	1	946	108	0
44.0010	MCLAREN-LAPEER REGION	H	1	104	10	0
HSA 5: GENESEE-LAPEER-SHIAWASSEE	5 Facilities		6	2,283	421	0
29.0010	MIDMICHIGAN MEDICAL CENTER- GRATIOT	H	1	93	16	0
37.0010	MCLAREN - CENTRAL MICHIGAN	H	1	44	8	0
73.6811	ST. MARY'S OF MICHIGAN TOWNE CENTRE	F	1	312	30	0
HSA 6: EAST CENTRAL	7 Facilities		7	590	59	21
24.0030	MCLAREN NORTHERN MICHIGAN HOSPITAL	H	1	146	43	0
69.0020	OTSEGO MEMORIAL HOSPITAL	H	1	96	36	0
HSA 7: NORTHERN LOWER	5 Facilities		5	701	90	0
52.0050	MARQUETTE GENERAL HOSPITAL	H	1	57	2	24
HSA 8: UPPER PENINSULA	3 Facilities		3	107	2	24
State Total	79 Facilities		82	12,708	1,491	527

The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section B of the survey.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building 66, Room 2621
Silver Spring, MD 20993

July 17, 2013

Anne Mitchell
Ae_mitchell@comcast.net

Document Number: CPT1300384

Dear Ms. Mitchell:

This is in response to your correspondence, dated June 13, 2013 in which you provided information on Urinary Extracorporeal Shock Wave Lithotripsy. In your correspondence you allege Urinary Extracorporeal Shock Wave Lithotripsy is unsafe and that it can destroy lungs, spleens, the pancreas, kidneys, and a normal heart rate.

Thank you for providing this information to the Food and Drug Administration (FDA). Information from regulated industry is often very helpful to us in identifying problems with marketed products and possible violations of the laws that we enforce. We take such reports seriously, and we will evaluate this matter to determine what follow-up action is appropriate. The type and extent of any follow-up is dependent upon the nature of the problem, the possible impact on the public health, and the availability of our resources.

While FDA does not provide information on ongoing investigations, information can be obtained pursuant to a Freedom of Information Act (FOIA) request, once an investigation is closed. Requests for this information can be submitted via the agency online FOIA submission address at http://www.accessdata.fda.gov/scripts/foi/FOIRequest/index.cfm or in writing to the following address:

Food and Drug Administration
Freedom of Information Staff
ELEM 1029
12420 Parklawn Drive
Rockville, Maryland 20857

If you have any questions regarding this letter, please contact me at 301-796-6117 and reference the above document number.

Sincerely yours,

Donna Engleman, BSN MS
Complaint Program Manager
Center for Devices and
Radiological Health

11:CV-10090
HON VICTORIA ROBERTS

000086

Anne Mitchell
PO Box 3249
Oak Park, IL 60303
February 10, 2014

Ms. Donna Engleman, BSN MS
Complaint Program Manager,
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Building 66, Room 2621
Silver Spring, MD 20993

RE: CDRH CPT1300384

Dear Ms. Engleman and the OC/FDA:

In continued effort to ensure my complaint is being viewed with the utmost care and critical eye at FDA and to highlight my assertions I am forwarding a copy of an article published by University of Michigan urologists in the heralded professional journal UROLOGY's "Health Outcomes Research" section. (Tan HJ, Wolf JS Jr, Hollenbeck BK, Ye Z, Hollingsworth JM. *Use of ureterescopy before and after expansion of lithotripter ownership in Michigan.* (2011) Urology 78: 1287-1291).

This "research" has no relative scientific or practical merit, no significance or utility other than to "protect the evidence" and divert attention away by hiding the truth about UESWL. There are outright lies in this publication, and I know because I was there. These authors are guiding the official conversation on the UESWL subject within a highly tainted body of published work in peer reviewed medical journals. This "research" is nothing more than a block by block building effort for continuing the published "research" precedent that will continue to support the UESWL Outfit's official party line. With the editorial comment from UROLOGY's editor, Dr. Nadler, this paper provides the perfect example supporting my claim that urologists in the USA have **handily crafted a powerful, national collaboration that is in fact really collusion in a deadly cover-up**.

First, there is nothing honest in this work that allows the reader to understand the importance about what truthfully happened. By simply assigning comparative study to the years 2004 and 2007, one cannot remotely ascertain a factual or significant comparison. These authors can make no claims whatsoever about *Health Outcomes* because they have not provided the easily obtainable facts behind their faulty and highly flawed assumptions. Or, perhaps they did find these facts and just really didn't like what they found. So they figured out a way around it.

11:CV-10090

HON VICTORIA ROBERTS

000037

- Formulation of the "non-provider UESWL ownership service entities," *("United Health Systems and American Kidney Stone Management subsidiaries")* were completed in 2006, but due to many other factors, including the methodical Michigan Certificate of Need process, the full operations and expansion of these actual UESWL services were not yet completed even in 2007.

- In 2004, in preparation for the hostile takeover of UESWL services in Michigan that took place by these entities during 2005-2006, the urologists had already long been conspiring together to substantially ramp up use of UESWL within existing services in order to satisfy and meet patient volume requirements within the Certificate of Need statutes for achieving their over-arching plan for a massive statewide UESWL service expansion.

- There is a one-two year lag time in order to provide the Michigan Certificate of Need Department the volume evidence necessary to permit expansion of UESWL services.

- The only way these authors might have been able to draw meaningful comparison therefore in order to draw their conclusions would have been to compare the data from both URS (ureteroscopy) and UESWL in the years first between 2000-2003, and then between 2008-2011. The reason for this is that there was already excess capacity in the Michigan system available from those services already providing UESWL during 2000-2003. In so doing, these authors might have chosen to provide valid and truthful data and would then have achieved statistical significance and meaningful comparison.

I would first like to say this: These authors are extremely smart people. They operate within a university academic medical environment with extraordinary resources like biostatisticians and public health experts, highly accomplished expert strategic planners, a serious state public health system, and a unique capacity to elucidate critically important science, if only they intended that. This meaningless work demonstrates their clear intention was not that. Instead they continue over and over again in this case as do the others in the Outfit in a relentless effort to deploy non-clinical evidence to support their personal business interests. This is so easily done by manipulating what otherwise might be the actual valid science into that which appears scientific but is totally worthless and not actionable.

The authors assert there is a lack of empirical work on the relationship between physician ownership and technology substitution. This is only true because they hold all the cards and all the power to make it true. These authors would have you believe that there is no explicit or implicit money bias in medicine when physicians have non-provider ownership interest. They carefully manufactured this useless study to support the Outfit's party line that keeps all the money flowing.

Because they are under attack as they describe in the paper's objectives and comments, and there is no one within the medical or legal community who will stand up to them, they are able to continue to soldier on in the most ideal arrangement possible for them– to be both judge and jury of all their actions. There is no authority who will scrutinize them. They control the purse strings and the legislation now, because they have purchased it with the money they have stolen from the system and their patients. They control the research and what is published, and therefore they control the entire conversation concerning patient consent. They have amassed this power on a frightening scale. Real people are being exploited by this collusion in extremely harmful ways, and real people are dying because of this outrageous scheme.

So, here are the most despicable aspects of this biased and highly flawed and tainted publication:

- The authors state that "personal communications" from one of the two Michigan UESWL providers suggests that more than half of Michigan urologists participate in the ownership of UESWL service. This is actually true, but a statement of "more than half" is highly deceptive. It is actually also true that nearly <u>all</u> actively practicing urologists and nearly all those who perform UESWL in Michigan participate in the ownership of UESWL service. I know this, and I have the data.

- The authors used the Michigan SASD as their data source. This does not reflect reality in Michigan. And it does not remotely reflect reality in the years for 2004 and 2007 for the subject at hand. Because although it is readily available, they reveal no UESWL data.

- They demonstrated, but not remotely completely, just how money-driven and profit-centric their patient selection for the UESWL procedure was. If you have money or good insurance you will be selected and "sold" the UESWL procedure.

- The authors provided only a nod to the fact that URS may have increased, even entirely as a matter of failures of the UESWL procedure. It may have increased because of the FACT that UESWL volume increased by more than thirty percent! However, they never tell you this. First they carefully selected 2004 and 2007 as the years in the study, and next, even though all the data exist within the *Michigan Department of Community Health Certificate of Need Section* about the volume of patients treated and retreated in Michigan for UESWL by year as a matter of policy, they kind of just forgot to mention this critical fact in the paper. And who outside of Michigan would ever know the difference? They simply did not reveal the most highly consequential and critical facts needed to formulate accurate conclusions in their study.

- The paper reads like science, but apparently even the IRB at Michigan wouldn't touch it with a ten foot pole. It is full of total nonsense. Nonetheless, now it will

be cited to support the heist because the scientific authorities within the United States' practice of urology found it useful to publish. Nothing of any medical, scientific, or human value whatsoever supports the authors' conclusions. Nothing of any reasonable merit whatsoever. But American urology journal's editorial boards make sure such pure deception gets published, to uphold the UESWL racket.

- The authors assume that URS and UESWL are substitutable. They never tell you the drama of the increase of the use in UESWL once the urologists became "owners," even though the data for this is readily available in Michigan.

The comments by the editor are just as surreal.

- Was this a nice political nod by Dr. Nadler to the University of Michigan's Department of Urology? Was this just a mutual back-scratch? He also states that "urologists have always been at the forefront of medical and financial innovation." He actually suggests that the authors of this "study" should "be applauded for asking the tough but obvious questions for which everyone wants to know the answers." Anyone of any scientific authority whatsoever can see the very distinct and cowardly nature of this "study." None of the most important and valid questions were asked, and therefore there were absolutely no answers to any concerns whatsoever.

- Nadler has not remotely scrutinized that the stable/increased rates of URS are likely directly related to substantially increased performance rates of UESWL that are not at all described in a statistically significant manner! This is a highly likely cause for these results, and is a very serious cause for a cost and quality of care concern! This publication is trying to make a comparison, but not including the relevant comparative data! Who is this "Editor?" **We cannot trust what is published in the medical literature about this subject. It is badly damaged. There is not one iota of objectivity here across the board.**

- There is actually research in the literature that "measures" just how much patients love the UESWL procedure! They love it because they have not been told the truth, and are unable to connect the dots from UESWL to the adverse effects they suffer.

This one paper alone demonstrates the degree to which urologists in this massive nationwide UESWL scheme are masterfully mocking their responsibilities and instead engaging in the ultimate game of CYA. These men have clear knowledge of where all the bodies are buried, and they have mastered the art of mob/pack mentality to bolster a cover-up of dramatic and deadly proportion: All for the money.

Please be the one hope that this will properly, scientifically, and morally be scrutinized. People are dying. All this deception and exploitation of the sick and vulnerable is costing a fortune.

Thank you very much.

Sincerely,

Anne Mitchell

Use of Ureteroscopy Before and After Expansion of Lithotripter Ownership in Michigan

Hung-Jui Tan, J. Stuart Wolf, Jr., Brent K. Hollenbeck, Zaojun Ye, and John M. Hollingsworth

OBJECTIVE To determine whether ureteroscopy (URS) rates decreased following the expansion of lithotripter ownership in Michigan. Historically, Michigan has had limited urologist investment in lithotripters owing to strict Certificate of Need legislation. However, 2 of the nation's largest lithotripsy providers formed Michigan subsidiaries in 2005 and 2006, thereby altering the ownership landscape. Urologists who acquired partnership shares were incentivized to perform shock wave lithotripsy preferentially over URS. Because of ownership expansion, the rates of URS might have decreased.

METHODS From the Michigan files of the State Ambulatory Surgery Database, we abstracted the discharges for URS performed at hospital-based outpatient departments. We measured the differences between the patients who underwent URS in the year before (2004) and the year after (2007) ownership expansion. We then calculated the annual rates of URS in Michigan and evaluated for changes over time.

RESULTS A total of 5857 and 6294 URSs were performed in 2004 and 2007, respectively. Significant differences in age ($P < .001$), race ($P < .001$), primary payer ($P < .001$), and comorbidity status ($P < .001$) were observed between the patients who underwent URS before and after ownership expansion. However, the rates of URS in Michigan remained relatively flat despite the increased urologist ownership of lithotripters ($P = .129$ for the temporal trend).

CONCLUSION The introduction of physician ownership of lithotripter units in Michigan was not associated with decreased rates of URS but might have influenced treatment selection among certain patient groups. UROLOGY 78: 1287–1291, 2011. Published by Elsevier Inc.

With reimbursement for professional services declining and practice costs increasing, more and more physicians are seeking nontraditional revenue streams as a method of recouping some of their lost income.[1] These efforts have sparked an increase in physician entrepreneurial activity. As a result, physician investments in specialty care facilities and ancillary services technology have spread and diversified greatly over the past decade.[2] Specific to urology, ownership in lithotripsy ventures has become an important source of income for most urologists in the United States.[3]

Although physician-owned ventures have potential benefits (eg, an opportunity to improve patient outcomes by controlling the operation and quality of the service or treatment), such arrangements incentivize physicians to use the facility or technology that they own. Indeed, urologist ownership of ambulatory surgery centers (ASCs), including lithotripsy centers, has been linked to increased shock wave lithotripsy (SWL) use.[4,5] While this increased use may be explained by increased capacity and unmet demand, expanding treatment indications and technology substitution (whereby owners preferentially perform a procedure requiring their specialized equipment versus one that does not) may also contribute. The latter could pose a potential quality of care concern if financial incentives steer physicians toward the selection of a particular treatment when other approaches are available and might be preferable.

The published literature is replete with examples of increased health services use associated with physician ownership,[4-10]; however, there is a lack of empirical work on the relationship between physician ownership and technology substitution. To fill this knowledge gap, we analyzed population-based data from Michigan from 2004 to 2007. During this period, 2 of the nation's largest mobile lithotripsy providers formed subsidiaries in Michigan and offered partnership stakes for SWL to the

From the Dow Division of Health Services Research and Division of Endourology and Stone Disease, Department of Urology, University of Michigan, Ann Arbor, Michigan

Reprint requests: John M. Hollingsworth, M.D., M.S., Department of Urology, University of Michigan, North Campus Research Complex, 2800 Plymouth Road, Building 520, 3rd Floor, No. 3170, Ann Arbor, MI 48109-2800. E-mail: kinks@med.umich.edu

Submitted: January 3, 2011, accepted (with revisions): May 28, 2011

Published by Elsevier Inc.

0090-4295/11/$36.00

doi:10.1016/j.urology.2011.05.070